Assessment Date: July 13, 2011

DOH Laboratory #: E82001

DEP Purchase Order #: A422A9

Laboratory Name: Advanced Environmental Laboratories
6815 SW Archer Road
Gainesville, FL 32608

I. Introduction

An onsite evaluation of the laboratory was conducted to verify compliance with the purchase order requirements of **DEP Purchase Order No.** A422A9**,** which incorporates adherence to the quality control requirements in Chapter 5 of the NELAC Standards, Standard Methods 20th edition, section 9020 (SM9020), Chapter 62-160, Florida Administrative Code (F.A.C) and continued accreditation with Florida Department of Health under the National Environmental Laboratory Accreditation Program (NELAP) for fecal coliform bacteria. The audit consisted of an introductory conference, discussion of laboratory operations, review of selected analytical records for parameters contracted by the FDEP, a walk-through of the laboratory facility, and an exit interview with key laboratory staff. It is noted that a complete review of the sample handling from receipt to data evaluation and delivery to FDEP was conducted.

II. Personnel

The following personnel participated in the laboratory audit:

FDEP Auditor	Position	Contact Information
Daisys Tamayo	Environmental Supervisor II	850-245-8162
Michele Reliford	Environmental Specialist II	850-245-8066

Advanced Environmental Laboratories

Personnel	Position	Contact Information
Karen Daniels	Laboratory Manager	352-377-2349
Amanda Ireland	Receptionist	352-377-2349
Lindsey McLeod	Analyst	352-377-2349

III. Evaluation and Observations

Upon arrival at the lab, FDEP staff met with Karen Daniels. Information on the operations of the laboratory was provided by Karen Daniels. It was determined that the education and technical experience of laboratory staff are adequate for the microbiological tests being conducted.

The facility, documentation, and procedures were inspected for the following methods covered under the current purchase order:

Analysis: Fecal Coliforms Method: SM9222D

The laboratory was clean, uncluttered, and adequate for conducting the contracted parameters. No concerns or deficiencies were noted.

FDEP staff reviewed tracking records from sample receipt through sample disposal, data analyses and the electronic data deliverable records for FDEP reimbursement. One minor deficiency was noted and is listed below (Table 1).

Documentation for the following samples analyzed under purchase order was reviewed for completeness and accuracy. Two dilutions were performed for samples reviewed. This deficiency was addressed in May 2011 by Diane Power. FDEP samples for subsequent dates were further reviewed and were analyzed using 3 dilutions (See checklist comment 1). Since the correction was made prior to the audit, no deficiency was reported.

FDEP LIMS Job ID	AEL Report ID	Date Sampled	Date Analyzed	# of samples	Analysis
TLH-2011-02-02-12	1102038	2/1/11	2/1/11	5	Fecal Coliforms
TLH-2011-04-07-45	1104156	4/6/11	4/6/11	5	Fecal Coliforms

Reports were found to be complete and adequately reviewed for correctness. No deficiencies were noted. The Electronic Data Deliverables are submitted in the correct tab delimited format, but do not include all required elements in the order listed in FDEP Purchase order # A422A9 Attachment A. (See checklist comment 4). For example, the Received Date and Time elements are not included in the EDD and date and times for sample collection and analysis are not in separate fields. The current LIMS system does not allow for changes in the EDD. The facility will be updating to a new LIMS system soon, and will possibly be able to update the EDD.

IV. Deficiencies Noted and Corrective Action Required

Deficiencies are listed in Table 1: Deficiencies and Corrective Action provided below. Corrective action plans and completion dates should be identified on the form and returned to DEP within 45 days of receipt of this Audit Report.

A copy of the evaluation checklist utilized during the on-site assessment is attached as Appendix A. Comments from the checklist are referenced in the Statement of Deficiencies.

One deficiency was noted during the audit. The Laboratory is advised to correct all deficiencies as soon as possible but no later than the allowable 45 day response time per QA rule 62-160.650.

Note that if the required corrective actions are not addressed in a timely manner, this may result in the FDEP invalidation of data generated under this purchase order which would result in payment for services rendered being declined.

V. Summary

Based on the information collected and reviewed, the on-site evaluation of the laboratory, and the review of the reports and electronic data deliverables evaluated during the Overflow Laboratory for Microbiological Analyses Audit on July 13, 2011 by the Florida Department of Environmental Protection Biology and QA Staff, Advanced Environmental Laboratories is generally meeting the conditions of the purchase order with the exception of the deficiency noted.

TABLE 1: Deficiencies and Corrective Action

Deficiency #	Statement of Deficiency	Proposed Corrective Action	Completion Date
1	Samples that undergo verification procedure are not reported as "Verified". [DEP Purchase Order #A422A9, Attachment B Section IV.3.b] *See checklist comment 2.*		
2			
3			
4			

Appendix A

Date: July 13, 2011

Lead Auditor: Daisys Tamayo

Additional Auditor: Michele Reliford

Analysis	Method
Fecal Coliform	SM9222D
Enterococci	N/A

Laboratory Name:	Advanced Environmental Laboratories (AEL)	Certification#:	E82001
Primary Contact:	Karen Daniels	Phone Number:	352-377-2349
Address:	6815 SW Archer Road Gainesville, FL 32608		
Email:	kdaniels@aellab.com		

Position Title	Name	Phone	Email	Job Responsibilities
Laboratory Manager	Karen Daniels	352-377-2349	kdaniels@aellab.com	Oversees all aspects of laboratory operations. Responsible for laboratory quality assurance and quality control
Receptionist	Amanda Ireland	352-377-2349	aireland@aellab.com	Sample custodian
Technician/Analyst	Lindsey McLeod	352-377-2349	lmcleod@aellab.com	Microbiological analysis and data processing

Reports to Review:

Job ID	*Report ID*	*Date Sampled*	*Date Analyzed*	*# of samples*	*Documents reviewed:*
TLH-2011-02-02-12	*1102038*	*2/1/11*	*2/1/11*	*5*	✓*Custody sheet* ✓*Sample Receipt Log* ✓*Raw Data Log* ✓*Final Report* ✓*EDD*
TLH-2011-04-07-45	*1104156*	*4/6/11*	*4/6/11*	*5*	✓*Custody sheet* ✓*Sample Receipt Log* ✓*Raw Data Log* ✓*Final Report* ✓*EDD*

Sample Receipt (NELAC 5.5.8)

✓	Sample Acceptance Policy made available to sample collectors.
✓	Chlorine check performed on appropriate samples.
✓	Samples stored under refrigeration if not analyzed immediately.
Documentation:	
✓	Date/Time Received
✓	Sample Container Check
✓	Temperature Check (≤10 °C)
✓	Improperly preserved samples are “Y” qualified.

Additional comments:

Laboratory Facility (NELAC D.3.8, SM9020B)

✓	Walls, floors, and work surfaces are non-absorbent, and easy to clean and disinfect.
✓	Lab well ventilated and free of dust and drafts.
✓	Monitor air density (15 colonies/plate/15 min) and bench surface contamination.
✓	Lab space clean and free of clutter.
✓	Plants, food, and drinks are prohibited in the lab.

Additional comments:

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Media (NELAC 3.1, 3.6, SM9020B)

✓	Sterility check run for each batch of prepared media or each lot of ready-to-use media.
✓	Positive control run for each batch of prepared media or each lot of ready-to-use media.
✓	Negative control run for each batch of prepared media or each lot of ready-to-use media.
✓	Open media bottles stored away from moisture and used within 6 months from open date.
✓	Expiration date (2 weeks for agar plates, loose cap tubes; 96 hrs for broth in screw cap flasks, 3 months for screw cap tubes.
Documentation:	
✓	pH check of media
✓	Media bottles used and amount

Additional comments:

Equipment and supplies (NELAC D.3.8, SM9020B)

Autoclave

✓	Record contents, temp, sterilization time, total run time, and analyst for each cycle.
✓	Chemical steam indicator used for each cycle (autoclave tape).
✓	Biological (*Geobacillus stearothermophilus*) check performed monthly.
✓	Timer checked quarterly.

Waterbaths

✓	Temp maintained at 44.5 ± 0.2° C for fecal coliforms. (Checked twice daily).
✓	Cover and/or circulation pump used to prevent evaporation and maintain even temp.
✓	Racks/weights used to prevent samples from floating.
✓	Waterbath emptied and cleaned periodically.

Incubators

✓	Temp maintained at 41.0 ±0.5 °C for enterococci, 35.0± 0.5°C and 45.0 ±0.5°C for verification of fecal coliforms and enterococci.
✓	Thermometer submerged in water or glycerin.
✓	Samples not overcrowded and provided sufficient airflow when placed in incubator.
✓	Incubator cleaned and sterilized periodically.

pH meter

✓	Meter graduated in 0.1 pH units or less and includes temperature compensation.
✓	Calibrated with 2 buffers that bracket pH being measured.

UV lamps

✓	Lamps cleaned monthly with ethanol.
✓	Tested quarterly with a light meter (output >70%) or by biologicals (99% reduction).

Thermometers

✓	Calibration checked at least annually with NIST certified thermometer.
✓	Calibration correction factors marked on thermometer as needed.
✓	Thermometer has appropriate graduated increments for use.
✓	Thermometer in good working condition and free of separations in liquid column.
✓	Temperature checked twice daily at least four hours apart for working incubators/water baths.

Glassware and Supplies

✓	Check pH with bromothymol blue for each batch of washed glassware.
✓	Inhibitory residue test performed annually or after a change in detergent lot or washing procedure. (SM9020 requires test only with initial use of compound or change in procedure if BTB pH check is done consistently.
✓	Sterility checks performed with each lot of sample container, membrane filters and pads, and dilution water bottles (also require pH and volume check).
Laboratory Water	
✓	Run the following water quality checks (See Table 1):

Additional comments:

Membrane Filtration (NELAC 3.1, SM9020B, SM9050C, SM9222D, EPA 1600)

✓1	Three dilutions analyzed per sample.
✓	Control Blanks analyzed at beginning and end of each filtration series.
✓	Control blank run after every ten samples, unless UV sterilized.
✓	Duplicates analyzed on 10% of samples, at least one every batch.
✓	Phosphate buffered water used for rinse, dilutions, laboratory blanks. PBS may be used for EPA 1600.

Documentation:

✓	Filtration time
✓	Incubation Start Time
✓	Incubation End Time

Additional comments:

1. Two dilutions (10, 100 mL) were analyzed for the samples selected for review. Per emails between Diane Power and Karen Daniels, this deficiency was addressed in May 2011, prior to the audit. Subsequent samples were reviewed and documentation shows that 3 dilutions are currently being analyzed.

Verification (NELAC D.3.4, SM9020B, SM9222D, EPA 1600)

✓	Verify at least 10 colonies from a positive sample per month (per Table 3).
✓	Verify atypical or ambiguous colonies of different morphological types to check for false negatives.
✓	Adjust colony count based on percentage of verified colonies.
2	For samples that are subject to verification process as "Verified"

Additional comments:

2. Samples that have been verified are not reported as “Verified” in the final report.

Demonstration of Capability (NELAC D.3.2, SM9020B)

✓	Participates in a proficiency testing program (analyze PT's 2x/yr).
✓	Each analyst has documentation of demonstration of capability (initial and annually).
✓	Comparison of colony counts performed monthly. (<10% difference btwn 2 analysts, <5% for 1 analyst)

Additional comments:

Data Handling (Chapter 62-160 F.A.C., SM9020B, SM9222D, EPA 1600)

✓	Samples that are exceed holding time requirements are "Q" qualified.
✓	Samples that exceed incubation time limits are "J" qualified.
✓	Samples that are associated with a failed QC are qualified (blanks, replicate failures).
✓	Results are calculated per method and contract requirements.
✓	Ideal colony count range is 20-60 (fecal and enterococci) per membrane.
✓	Samples with no dilution in ideal range are "B" qualified.
✓	Calculation of MDL (dilution factor or min. reporting limit) based on acceptable dilutions.
✓	Control charts maintained for lab replicate samples and used to determine precision criteria.
✓3	Data entry process includes a verification step to minimize transcription errors.
✓4	Electronic data deliverable meets contract requirements.

Additional comments:

3. Analyst enters data including qualifiers manually. Lab Manager reviews LIMS data and verifies against the raw data before approving report. 4. Not all elements are included in the EDD. The current LIMS system is not able to change the format of the EDD, but the laboratory is moving to a new facility and the updated LIMS system may allow for alterations in the EDD.

Table 1. Laboratory Water Requirements

Analysis	Frequency	Exceptable Limits
pH	with each use (not required for Online Edition -05)	5.5-7.5
Conductivity	with each use	< 2.0 umho/cm
TRC	monthly	< 1.0 mg/L
HPC	monthly	<1000 CFU/mL
NH3, Organic N	monthly (not required for Online Edition -05)	<0.1 mg/L
TOC	monthly	< 1.0 mg/L
Use test	quarterly or for new water source	student's t < 2.78
Metals	Cd, Cr, Cu, Ni, Pb, Zn annually	each <0.05 mg/L, total <0.1 mg/L
Bacteriological ratio	annually (not needed for type II (medium) water quality or better, see Table 2)	0.8 - 3.0

Table 2. Water types per SM1080C

	High	Medium
Types	1	11
Resistivity (megaohm-cm)	> 10	> 1
Conductivity (umhos/cm)	< 0.1	< 1
SiO2, mg/L	< 0.05	< 0.1

Table 3: Verification Tests

Method	**Verify with the following:**					
Enterococci EPA 1600	BHI Agar Slant 35 ± 0.5°C 48 ± 3 h (use growth for gram staining)	BHI 35 ± 0.5°C 24 ± 2 h (turbidity)	Gram stain (gram positive cocci)	BHI 45 ± 0.5°C 48 ± 3 h (turbidity)	BEA 35 ± 0.5°C 48 ± 3 h (growth w/ black/brown precipitate)	BHI w/6.5% NaCl 35 ± 0.5°C 48 ± 3 h (turbidity)
Fecal Coliforms SM9222D	LTB 35 ± 0.5°C 48 ± 3 h (turbidity and gas)	EC 44.5 ± 0.2°C 24 ± 2 h (turbidity and gas)				

( ) Positive result for each test in parenthesis.

Table 1

Reporting Requirements:

Field	Format	Required	Comments
Contract Lab Identifier	Varchar2(20)	X	DOH Certification Number of Contract Laboratory
LIMS Request ID	Varchar2(20)		Not used by our matching algorithm but potentially useful for reference
Field ID	Varchar2(50)	X	Bar-coded information (eventually). Might be Field-ID, sequestial number or a combination of both.
Site Location	Varchar2(80)		Sample collection location
STORET Station	Varchar2(20)		STORET Station Identifier
Contract Lab Sample ID	Varchar2(x)	X	Contract Lab Sample ID - not useful for us but potentially useful for refernce. No character limitation.
Date Sampled	mm/dd/yyyy	X	Date sample was collected.
Time Sampled	hh24:mm	X	Time of sample collection, in military format.
Date Received	mm/dd/yyyy	X	Date the sample was received by the contract laboratory.
Time Received	hh24:mm	X	Time received by the contract laboratory, in military format.
Analysis Start Date	mm/dd/yyyy	X	Date of placement of the processed sample into or on the applicable growth medium.
Analysis start Time	hh24:mm	X	The time of placement of the processed sample into or on the applicable growth medium, in military format.
Analysis End Date	mm/dd/yyyy	X	Date the sample was read by the contract laboratory.
Analysis End Time	hh24:mm	X	Time read by the contract laboratory, in military format.
Contract Lab Test ID	Varchar2(80)	X	Overflow lab's test ID - will be mapped to B/Labs Test ID
Contract Lab Compound	Varchar2(80)	X	Overflow laboratory's analyte name - will be mapped to B/Labs component name.
Units	Varchar2(10)	X	Overflow laboratory's units
Result	Varchar2(20)	X	Must be a numeric expression (no<, >, etc); Stored as test to preserve significant figures.
Qualifier		if appropriate	Must match those in the QA Rule (Chapter 62-160 F.A.C.); multiple qualifiers concatenated with no spaces or characters in between.
Dilution Factor	Varchar2(10)		Must be numeric expression.
MDL	Varchar2(10)		Must be numeric expression.
PQL	Varchar2(10)		Must be numeric expression.
Comments	Varchar2(80)		

Electronic Data Deliverables:

The Contractor must report the data in the electronic format described above unless both parties mutually agree otherwise.

The Electronic Data Deliverable must be a flat file with the field delimited by tabs. For the items that are not required and not available, the delimiters must still be included.