Florida Department of Environmental Protection

Bob Martinez Center
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

Rick Scott
Governor

Jennifer Carroll
Lt. Governor

Herschel T. Vinyard Jr.
Secretary

October 5, 2011

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Trish Jackson, President
5808 East Highway 221
Panama City, Florida 32404

Dear Ms. Jackson:

Enclosed is a copy of the FDEP Overflow Contract Laboratory Microbiological analyses Inspection conducted at The Water Spigot, Panama City location on August 9, 2011.

I am requesting that you respond to us in writing within 45 days of receipt of this letter (and attachments), stating in detail what actions have been taken by the laboratory regarding the deficiencies noted in the enclosed inspection report. Your response should include the information requested in Table 1 of the inspection report and should be mailed to:

Daisys Tamayo
Florida Department of Environmental Protection
Biology Section MS #6515
2600 Blair Stone Road
Tallahassee, FL 32399-2400

If you have any questions or comments, please contact Daisys Tamayo at (850)245-8162.

Sincerely,

David D. Whiting,
Program Administrator, Biology Section

Enclosure

CC: Michael Blizzard, FDEP
Michelle Reliford, FDEP

DDW/dt

Assessment Date: August, 9 2011

DOH Laboratory #: E81105

DEP Purchase Order #: A4221

Laboratory Name: The Water Spigot
5808 East Highway 221
Panama City, FL 32404

I. Introduction

An onsite evaluation of the laboratory was conducted to verify compliance with the requirements of **DEP Purchase Order No.** A4221, 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 and enterococci 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

Daisys Tamayo	Environmental Supervisor II	850-245-8162
Michele Reliford	Environmental Specialist II	850-245-8066

The Water Spigot

David Beall	Laboratory Director	850-871-1900
Darrel Halsell	QA Officer	850-871-1900
Sally Martin	Supervisor/Primary Analyst	850-871-1900
Lilly Striplin	Laboratory Analyst/Tech	850-871-1900

III. Evaluation and Observations

Upon arrival at the lab, FDEP staff met with David Beall, Darrell Halsell, and Sally Martin. Information on the operations of the laboratory was provided by Sally Martin. 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:

Fecal Coliforms	SM9222D
Enterococci	EPA 1600

Although the laboratory has been approved for the analyses of enterococci, the laboratory is not presently running this analysis under the current purchase order. Therefore, specific data were not available for review. However, general procedures, equipment, and logbooks for enterococci analysis were reviewed.

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

FDEP staff reviewed tracking records from sample receipt through sample disposal, data analyses and the electronic data deliverable records for FDEP reimbursement. Two major and four minor deficiencies were noted and are listed below (Table 1).

Documentation for the following samples analyzed under purchase order was reviewed for completeness and accuracy. The original report for these samples reported results with an "I" qualifier. A corrected report was submitted with appropriate "B" qualifiers before the audit. The laboratory is currently using "B" qualifiers and therefore will not be noted as a deficiency. No deficiencies were noted with respect to specific sample data reviewed.

FDEP LIMS Job ID	The Water Spigot Report ID	Date Sampled	Date Analyzed	# of samples	Analysis
TLH-2011-07-19-32	WS11JUL18-028	07/18/11	07/18/11	2	Fecal Coliforms

Reports were found to be complete and adequately reviewed for correctness. The Electronic Data Deliverables are submitted in the correct tab delimited format and include all contract required elements in the order listed in FDEP PO#A4221 Attachment A. No deficiencies were noted with respect to final reports and data deliverables.

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.

Two major and four minor deficiencies were noted during the audit. The two major deficiencies noted are deficiency #2 and #5 and if not corrected immediately will affect data acceptability by the FDEP. 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 August, 9 2011 by the Florida Department of Environmental Protection Biology and QA Staff, The Water Spigot is generally meeting the conditions of the contract with the exception of the deficiencies noted. However, final assessment of whether or not the laboratory meets the minimum criteria for data quality required by FDEP Purchase Order #A4221 cannot be made until deficiencies #2 and #5 are resolved.

TABLE 1: Deficiencies and Corrective Action

Deficiency #	Deficiency Type	Statement of Deficiency	Proposed Corrective Action	Completion Date
1	Minor	Air density plates are not evaluated to determine if results meet or exceed limits. [20th ed. SM9020 B.2.e] *See checklist comment 1.*		
2	Major	Beginning time of incubation is not recorded. [DEP Purchase Order #A4221, Attachment B Section II.B] *See checklist comment 2.*		
3	Minor	Verification process does not follow method requirements. [20th ed. SM9222D.2.f; DEP PO#A4221, Attachment B Section III.B.3.] *See checklist comment 3.*		
4	Minor	Monthly plate count comparison is not evaluated to determine if results meet or exceed variability requirements. [20th ed. SM9020 B.8.a.2); NELAC Appendix D.3.2] *See checklist comment 4.*		
5	Major	The correct desired colony count range of 20 – 60 fecal coliform colonies is not used. [20th ed. SM 9222D.2.a; DEP PO#A4221, Attachment B Section III.B] *See checklist comment 5.*		
6	Minor	Evaluation of duplicate analyses not based on precision criteria that is derived from the range of log transformed duplicates. [20th ed. SM9020 B.8.b.; DEP PO#A4221, Attachment B Section IV.C.2.] *See checklist comment 6.*		

Appendix A

Date:	August, 9 2011

Lead Auditor:	Daisys Tamayo
Additional Auditors	Michele Reliford

Analysis	Method
Fecal Coliform	SM9222D
Enterococci	EPA 1600

Laboratory Name	The Water Spigot	Certification#	E81105
Primary Contact	Trish Jackson	Phone Number	(850) 871-1900
Address:	5808 East Highway 221 Panama City, FL 32404		
Email:	trishj-waterspigot@comcast.net		

Position Title	Name	Phone	Email	Job Responsibilities
Laboratory Director	David Beall	(850) 871-1900	wspigot@comcast.net	Oversees all aspects of laboratory operations
QA Officer	Darrel Halsell	(850) 871-1900	waterspigot@comcast.net	Responsible for laboratory quality assurance and quality control
Supervisor/Primary Analyst	Sally Martin	(850) 871-1900	sally-waterspigot@cocmast.net	Microbiological analysis and data processing
Technician/Analyst	Lilly Striplin	(850) 871-1900		Secondary microbiological analysis, data review, and technician.

Reports to Review					
Job ID	Report ID	Date Sampled	Date Analyzed	# of samples	Documents reviewed:
TLH-2011-07-19-32	WS11JUL18-028	07/18/11	07/18/11	2	✓Custody sheet ✓Sample Receipt Log ✓Raw Data Log ✓Final Report ✓EDD
					✓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.
1.	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: 1. Air density plates are performed but not evaluated as pass or fail using established criteria.	

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	
N/A	Lamps cleaned monthly with ethanol.
N/A	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, single-use funnels, 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)	
✓	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.
✓	Sterility check per batch of dilution water used for rinse, dilutions, and laboratory blanks.
Documentation:	
✓	Filtration time
2	Incubation Start Time
✓	Incubation End Time
Additional comments: 2. The Incubation start time is not documented.	

Verification (NELAC D.3.4, SM9020B, SM9222D, EPA 1600)	
3	Verify at least 10 colonies from a positive sample per month (per Table 3).
3	Verify atypical or ambiguous colonies of different morphological types to check for false negatives.
3	Adjust colony count based on percentage of verified colonies.
3	For samples that are subject to verification process as "Verified"
Additional comments: 3. Verification is performed on 10% of the samples by streaking a plate and adding it to the same verification tubes instead of choosing 10 colonies monthly and streaking each colony into an individual tube.	

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).
4	Comparison of colony counts performed monthly. (<10% difference btwn 2 analysts, <5% for 1 analyst)
Additional comments: 4. Counts are not evaluated for variability as pass or fail.	

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.
5	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.
6	Control charts maintained for lab replicate samples and used to determine precision criteria.
✓	Data entry process includes a verification step to minimize transcription errors.
✓	Electronic data deliverable meets contract requirements.
Additional comments: 5. A colony count range of 20-80 is used for fecal coliforms. 6. Replicate results are not evaluated for precision and control charts are not maintained.	

Table 1. Laboratory Water Requirements		
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
	I	II
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

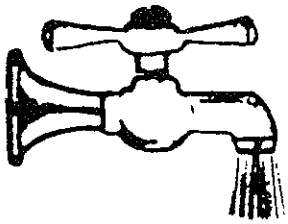
Reporting Requirements

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, sequential 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 reference. No character limitation
Date Sampled	mm/dd/yyyy	X	Date the 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 contact 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 text 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 a numeric expression
MDL	Varchar2(10)		Must be a numeric expression
PQL	Varchar2(10)		Must be a 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 fields delimited by tabs. For the items that are not required and not available, the delimiters must still be included.



the water spigot, inc.

NELAC Laboratory Certification #E81105

5806 East Hwy. 22 * Panama City, Florida 32404

(850) 871-1900 * Fax (850) 871-9303

trishj-waterspigot@comcast.net

Proposed Corrective Actions for Deficiencies	Completion Date
1. The length of time is now noted on bench sheets to make sure there is no more than one colony per minute of exposure on the plate.	August 10, 2011
2. Time in and out of the water bath is now noted on bench sheets.	August 10, 2011
3. The lab is now using the 10 colony method, and not the 10% positive plate method.	August 10, 2011
4. Two counts are now performed on plates by two people to ensure less than 10% variability between counts.	August 10, 2011
5. Correct colony count range is now being used. Any count outside of the range for the 100 ml sample volume is data qualified with a "B".	August 10, 2011
6. Evaluation of duplicate analyses will be based on precision criteria that is derived from the range of log transformed duplicates.	October 17, 2011

Trish Jackson, President — 10-10 2011 — Date

David Beall, Laboratory Director — 10-10-2011 — Date

Darrell Halsell, QA Officer — 10-10-2011 — Date