TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	5/17/2013
Department:	Technical staff	**Due Date:**	6/30/2013
		Implementation:	**7/1/2013**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Water, Purchased GEC / SGAH / WAH.QA23 v002

STA COMPACT Maintenance Log AG.F195.001

Description of change(s):

Section 3: Add Coag section documents lot number

Section 5: Update container sizes,
Add aliquot and labeling instruction,
Add on-board instrument process,
Remove filing of certificate,
Add lot number documentation and instruction to obtain certificate

STA COMPACT Maintenance Log - moved NERL water documentation (lot # recorded and verified) from weekly to **daily**

This revised SOP will be implemented on July 1, 2013

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 002)

Non-Technical SOP

Title	**Water, Purchased**	
Prepared by	Leslie Barrett	Date: 12/14/2009
Owner	Cynthia Bowman-Gholston	Date: 12/14/2009

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

This procedure outlines laboratory use of purchased water.

2. SCOPE

This procedure applies to all laboratory staff.

3. RESPONSIBILITY

Knowledge of this process is the responsibility of all laboratory staff.

Technical staff assigned to Coagulation section document purchased water lot number, and perform and record quality control.

The technical supervisor/manager is responsible to ensure compliance with this procedure.

4. DEFINITIONS

Reagent Grade Type I water: Type I water is “ideal” general purpose water that can be produced with currently available water treatment/purification technology. Type I water should be used in test methods that require minimal interference.

Acceptable QC: QC values within the expected or specified range for the test performed.

5. PROCEDURE

Water is an essential item needed in the Laboratory to perform and complete quality testing. It can be used to reconstitute controls, dilute reagents, calibrators, or patient samples, and can be used as negative controls themselves. In some instances, water is on-board a "walk-away" testing device to function as a rinse.

1. The available purchased water package size corresponds with the appropriate usage rate (Ranging from 1-pint to 5-gallon containers).

2. Date each water container upon opening and set the expiration date at 30 days after.

3. Water placed on-board a testing device (Centaur) or peripheral equipment (stainer) maintains a 30 day open expiration date. Label container with the lot number, date and time prepared, tech initials/code and expiration.

4. Aliquot a small vial of water for use to ensure consistent water quality and limit possible contamination of the primary bottle or container.
   a. Do not touch the lid or inside cover, or dip pipettes into the container.
   b. Do not return unused aliquots of water into the primary container.
   c. Aliquot into a sterile urine cup
   d. Label the aliquot with the lot number, date and time prepared, tech initials/code and expiration (24 hours from preparation)

~~5.~~ Document the lot number for purchased water used in coagulation on the appropriate maintenance log.
   Note: Purchased water is utilized throughout the Laboratory but the coagulation section is designated to maintain lot number documentation.

6. Evaluate the water quality as acceptable as long as the results of Coagulation quality control samples are acceptable.
   a. Follow the QC troubleshooting guidelines as specified in the Quality Control Program.
   b. If the water quality is identified as the root cause of the failure, the water is not satisfactory for use within the Laboratory. Segregate the lot of water and alert the supervisor or technical manager of the problem. The vendor maintains copies of the certificates of analysis for each lot number, on their website (http://www.nerl.com/certificate/coa.aspx), which may be printed as needed.

7. Document that the water remains fit for purpose throughout the entire period of use by
   a. Verifying the (In Use) lot number recorded on the appropriate Maintenance Log (Coagulation).
   b. Update the Maintenance Log whenever the water lot changes.
   c. Verifying acceptable performance of quality control as per the QC program.
   d. Refer to steps 6.a and b above.

8. In the event the Millipore water system should be out of service, the VISTA analyzers have a small onboard reservoir that can be used for continued testing. The Expand

analyzer will continue to function by filling the reservoirs with purchased water. Refer to step 3 above.

6. RELATED DOCUMENTS

Quality Control Program, QA procedure

7. REFERENCES

- Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline, 4th edition, CLSI Document C3-A4, 2006.
- Ken Petri, Director Industrial Testing, Quest Laboratories, Chantilly, VA.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L013.002		
000	2/15/12	Section 5: revise open dating to 30 days	A Chini	C Bowman
001	4/29/13	Section 3: Add Coag section documents lot number Section 5: Update container sizes, Add aliquot and labeling instruction, Add on-board instrument process, Remove filing of certificate, Add lot number documentation and instruction to obtain certificate	L Barrett	C Bowman

9. ADDENDA AND APPENDICES

None

Quest Diagnostics

☐ Germantown Emergency Center
☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

STA COMPACT Maintenance Log

Month: _____ Year: _____ Instrument Serial Number: _____

Daily	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Needle # 3 36.5 - 37.5 °C																															
Measuring Block 36.5 - 37.5 °C																															
Reagent Drawer 15 – 19 °C																															
Wash Solution																															
NERL Water Lot # :																															
NERL Water Lot # : *																															
SGAH & WAH only: Soak sample needle for 10 min in Desorb																															
Tech Initial																															

* used only if lot # changes

Weekly	**Week 1**		**Week 2**		**Week 3**		**Week 4**		**Week 5**	
	Date	Initial	Date	Initial	Date	Initial	Date	Initial	Date	Initial
Clean 2 air filters										
Clean washing wells -10% bleach										
Clean drawers and measurement plate – warm H_20, wipe dry										
Clean measurement and incubation wells with 20% ethanol on cotton swab. Remove any debris.										
Clean and inspect suction tip - warm H_20										
Perform needle purge										
Check liquid level in Peltier reservoir – fill with Glycol if necessary										
SGAH & WAH only: Soak sample needle for 30min in Desorb U										

Monthly	**Date**	**Initial**
Replace syringe tip and O ring		
Save Test Configurations to Disk		

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review: