TRAINING UPDATE

Lab Location:	SGMC, WOMC & GEC	**Date Distributed:**	1/20/2020
Department:	Core Lab	**Due Date:**	2/20/2020
		Implementation:	**1/27/2020**

DESCRIPTION OF REVISION

Name of procedure:

Water, Purchased SGAH.QA23 v4

Description of change(s):

Note: CQA cited the lab for not specifying the type of water used as a diluent in some of the SOPs. This SOP is revised to align water definition with CAP and CLSI

Header: Changed WAH to WOMC

Section 4: Specified CLRW with alternate name as 'reagent grade water'

Section 5: Added note for automated chemistry systems

Section 6: Added chemistry SOPs

Section 7: Updated CLSI document

This revised SOP was implemented January 27, 2020

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

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:	

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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 the 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.~~

Clinical Laboratory Reagent Water (CLRW) – water that meets CLSI requirements for ionic, microbiological and organic impurities, and particulate content.

Note: CLRW may also be referred to by the term Reagent Grade Water

Parameter	**CLSI / CAP specification for CLRW**
Bacterial content	≤10 CFU/mL (colony forming units per mL)
Resistivity	≥10 MΩ-cm (megohm-cm)
Particulate matter	0.22 µm filter
Organic contaminants	Total organic carbon (TOC) <500 ng/g*

* Not required by CAP

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 https://us.vwr.com/store/product/4544433/water-reagent-grade-nerl, 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. Updating the Maintenance Log whenever the water lot changes.
   c. Verifying acceptable performance of quality control as per the QC program. 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 Xpand analyzer will continue to function by filling the reservoirs with purchased water. Refer to step 3 above.

Notes: The Vista and Xpand water systems produce the same type of water which is used for online dilutions. Quality control of those systems is detailed in chemistry procedures (see Related Documents).

6. RELATED DOCUMENTS

Quality Control Program, QA procedure
Dimension Vista® Sample Processing, Startup and Maintenance, Chemistry procedure
Millipore (AFS – Analyzer Feed System), Siemens Dimension® Xpand, Chemistry procedure

7. REFERENCES

- Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline, 4th edition, CLSI Document GP40-A4-AMD, 2012 ~~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

Version	Date	Reason for Revision	Revised By	Approved By
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-Gholston
002	4/27/17	Header: Add other sites Section 5: Update web address in step 6 Footer: Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	C Bowman-Gholston
3	1/3/20	Header: Changed WAH to WOMC Section 4: Specified CLRW with alternate name as reagent grade water Section 5: Added note for automated chemistry systems Section 6: Added chemistry SOPs Section 7: Updated CLSI document	L Barrett	C Bowman-Gholston

9. ADDENDA AND APPENDICES

None