

AHC.QA23 Water, Purchased

Copy of version 5.0 (approved and current)

Last Approval or
Periodic Review Completed 11/24/2023

Next Periodic Review
Needed On or Before 11/24/2025

Effective Date 11/29/2021

Uncontrolled Copy printed on 2/19/2024 1:18 PM

Printed By Lydia Seifu

Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Periodic review	QA Leader approval	11/24/2023	5.0	Cynthia Bowman-Gholston MT(ASCP) (104987)	
Periodic review	QA approval	11/21/2023	5.0	Demetra Collier (110199)	
Approval	Lab Director	11/18/2021	5.0	Nicolas Cacciabeve	
Approval	QA Leader approval	11/17/2021	5.0	Cynthia Bowman-Gholston (104987)	
Approval	QA approval	11/15/2021	5.0	Leslie Barrett (104977)	
Approval	Lab Director	1/14/2020	4.0	Nicolas Cacciabeve	
Approval	QA Leader approval	1/14/2020	4.0	Cynthia Bowman-Gholston	
Approval	QA review	1/9/2020	4.0	Leslie Barrett	
Periodic review	QA Leader approval	4/5/2019	3.0	Cynthia Bowman-Gholston	
Periodic review	QA approval	4/4/2019	3.0	Leslie Barrett	
Approval Captured outside MediaLab	Lab Director	4/28/2017	3.0	Nicolas Cacciabeve	Recorded on 4/4/2019 by Leslie Barrett (104977) when document added to MediaLab
Periodic review Captured outside MediaLab	Designated Reviewer	4/28/2017	3.0	Nicolas Cacciabeve	Recorded on 4/4/2019 by Leslie Barrett (104977) when document added to MediaLab

Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.

Prior History

Updated prefix 11/30/21

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
5.0	Approved and Current	Major revision	11/15/2021	11/29/2021	Indefinite

4.0	Retired	Major revision	1/8/2020	1/27/2020	11/29/2021
3.0	Retired	First version in Document Control	4/4/2019	5/23/2017	1/27/2020

Uncontrolled copy
Current as of 2/19/2024 1:18 PM

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
<i>Refer to the electronic signature page for approval and approval dates.</i>		
Local Issue Date:		Local Effective Date:

TABLE OF CONTENTS

1. PURPOSE.....	1
2. SCOPE.....	1
3. RESPONSIBILITY	1
4. DEFINITIONS	2
5. PROCEDURE.....	2
6. RELATED DOCUMENTS	3
7. REFERENCES	3
8. REVISION HISTORY	3
9. ADDENDA AND APPENDICES.....	4

1. PURPOSE

This procedure outlines the use of purchased water in the laboratory.

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

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 chemistry instrument 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® EXL, Chemistry procedure
 Atellica Solution Operating, QC, Calibration and Maintenance, Chemistry procedure

7. REFERENCES

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

Version	Date	Reason for Revision	Revised By	Approved By
002	4/27/17	Header: Add other sites Section 5: Update web address in step 6 Footer: Version # leading zeros 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
4	11/15/21	Header: deleted site names, added All Labs Section 6: deleted Xpand SOP, added EXL and Atellica SOPs Footer: updated prefix to AHC	L Barrett	C Bowman-Gholston

9. ADDENDA AND APPENDICES

None

Uncontrolled copy
 Current as of 2/19/2024 1:18 PM