PURPOSE

This procedure outlines the use of purchased water, i.e. Clinical Laboratory Reagent Water (CLRW), in the laboratory.

SCOPE

This procedure applies to all laboratory staff.

RESPONSIBILITY

All laboratory staff are responsible for being knowledgeable of and adhering to this process. Technical staff who are assigned to the Coagulation section are responsible for daily documentation of CLRW lot number, and for the performance and recording of daily quality control results. The Technical Supervisor/Manager is responsible for ensuring compliance with this procedure.

DEFINITIONS

Clinical Laboratory Reagent Water (CLRW) refers to water that meets the CLSI requirements for ionic, microbiological and organic impurities, as well as particulate content. Please note that CLRW may also be referred to as Reagent Grade Water.

Table 1: CLSI Requirements for Clinical Laboratory Reagent 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 refers to obtaining QC values that are within the expected or specified range for the test performed.

PROCEDURE

In order for the laboratory to perform quality testing and maintenance procedures, water is an essential item that is often required. Water may be used for the reconstitution of control materials, the dilution of reagents, calibrators, or patient samples, and also may be used directly as negative controls. Additionally, water may sometimes be stored on-board some instruments as a "reagent" to function as a rinse.

- CLRW package sizes may be selected based on the relevant usage rate. Package sizes may range from 1-pint to 5-gallon containers.

- Upon opening, each water container should be labelled with both the open date and the expiration date. **Each container of CLRW expires 30 days after opening**.

- CLRW that is stored on-board an equipment also expires 30 days after opening. ***All containers must be labelled with the lot number, date and time prepared, Tech initials/code and the expiration date.***

- To avoid possible contamination of the primary bottle or container:

    - Aliquot a small amount of CLRW for use into an appropriately sized secondary container.

    - Be sure not to touch the lid or inside cover of the container

    - Do not dip pipettes into the container.

    - Do not pour unused aliquots of water back into the primary container.

    - Ensure that the containers into which portions are aliquoted are sterile, for e.g. a sterile urine cup.

    - Be sure to label all aliquots with the lot number, date and time prepared, Tech initials/code and date of expiration. **Aliquots expire 24 hours after preparation**.

- Using the appropriate maintenance log, document the lot number of the CLRW in use. Note: CLRW is utilized throughout the Laboratory but the Coagulation section is designated to maintain lot number documentation.

- Assess and document the water quality as acceptable, as long as passing Coagulation quality control results are obtained.
    - Adhere to the QC troubleshooting guidelines as outlined in the Quality Control Program.
    - If the water quality has been determined to be the root cause of QC failure, then the water is not satisfactory for use within any section of the Laboratory. The affected lot of water should be sequestered and the Supervisor or Technical Manager should be notified. Certificates of Analysis for each lot number may be found on the vendor website: https://us.vwr.com/store/product/4544433/water-reagent-grade-nerl. These may be printed as needed.
- Laboratory staff is responsible for daily documentation that the CLRW remains acceptable for use throughout the entire period of use by:
    - Verifying the lot number of the in use CLRW that has been recorded on the appropriate Maintenance Log in the Coagulation section.
    - Keeping the Maintenance Log updated by documenting each time the lot number changes.
    - Assessing and documenting acceptable performance of the Coagulation quality controls as per the QC program. Please refer to steps 6 a. and 6 b. above.

Notes: The water systems employed by the chemistry instruments are acceptable for use in performing on-board dilutions. Quality Control of those water systems is detailed in chemistry procedures (see Related Documents).

RELATED DOCUMENTS

1. ADM 108 – Quality Control Policy
2. Coagulation 102/Quality Control - Stago
3. DXC700 AU/153 - Maintenance
4. QA 102 – Reagent Labeling and Stability
5. QA/CORE LAB 100 – Core Lab Quality Management
6. QA/CORE LAB 105 – Quality Control

REFERENCES

1. Barrett, L. (2009). *Water, Purchased*. Adventist Healthcare.
2. Petri, K. Director Industrial Testing, Quest Laboratories, Chantilly, VA.
3. Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline, 4th edition, CLSI Document GP40-A4-AMD, 2012

APPENDICES

None.

ADMINISTRATION: VERIFICATION, APPROVAL & REVIEW

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Date	**Reviewer**	**Reason**	**Version Number**	**Signature**