HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Water Quality		
Applies To:	All Laboratory and Blood Bank Staff		
Preparation Date:	January 01, 2025	**Index No:**	LB-DPP-006
Approval Date:	January 15, 2025	**Version :**	2
Effective Date:	February 15, 2025	**Replacement No.:**	LB-DPP-006(1)
Review Date:	February 15, 2028	**No. of Pages:**	03

1. PURPOSE:

1.1 This policy provides direction for the processes and procedures to effectively ensure that all water used in the laboratory meets the correct required standards.

1.2 This is based upon requirements for specific tests, procedures, instrumentations or laboratory. The laboratory should have an adequate supply of needed water

2. DEFINITONS:

2.1 The Clinical Laboratory Reagent Water (CLRW) suitable for most laboratory procedures:
- 2.1.1 Type I: CLRW having a minimum resistivity of 10 MQ/cm
- 2.1.2 Type II: CLRW having a minimum resistivity of 1.0MQ/cm
- 2.1.3 Type III: CLRW having a minimum resistivity of 0.1 MQ/cm

2.2 Special Reagent Water (SRW): defined by a laboratory for procedures that need different specifications.

2.3 Resistivity in water is the measure of the ability of water to resist an electrical current, which is directly related to the amount of dissolved salts in the water. Water with a high concentration of dissolved salts will have a low resistivity, and vice versa.

3. POLICY:

3.1 The quality (specifications) of the laboratory's water, whether prepared in-house or purchased, must be checked and documented at least annually.

4. PROCEDURE:

4.1 Background Information: The unique ability of water to dissolve, to some extent, virtually every chemical compound and support practically every form of life means that raw water supplies contain many contaminants. The major categories of impurities found in raw water include:
- 4.1.1 Dissolved inorganic salts
- 4.1.2 Dissolved organic compounds
- 4.1.3 Micro-organisms
- 4.1.4 Pyrogens
- 4.1.5 Dissolved gases

4.2 Clinical Laboratory Reagent Water (CLRW): should be pure enough to satisfy the requirements of most routine clinical laboratory testing. This type of water is usually used for the reconstitution of controls and reagents and with instruments using water for analysis. The requirement for microbial content, resistivity, Total Organic Content (TOC) and particulate matter are the same as Type I.

4.3 Instrument Feed Water: is intended for internal rinsing, dilution and water bath functions of automated instruments. The specification of this type of water must be confirmed with the manufacturer of a specific instrument.

4.4 Water supplied by a method manufacturer for use as a diluents or reagent: - This type of water must only be used as described by the product labelling for that system. This type of water cannot be used for CLRW or SRW unless it meets those specific requirements.

4.5 Commercially bottled, purified water must meet the required specifications for its intended use. The water should be packaged in a manner that protects it from environmental contamination or degradation during transportation and storage, and from the effects of the container itself. Note that any bottled water, no matter what type must include a lot number and expiration date as well as the values for resistively, microbial count, TOC and information on particulate control in addition to any other applicable parameters. Commercially bottled purified water may have met the specification for CLRW when bottled, but at use, the bottled water should be considered SRW with specifications set by the laboratory based on intended use. The laboratory must validate that the bottled water is fit for its intended purpose in clinical laboratory testing. If a bottle is opened and reused over a period of time, the laboratory must validate the water remaining in the bottle as fit for purpose throughout the entire period of use. Each new lot of bottled water must be validated for acceptable performance in the test procedures for which it will be used. Validations must include chemical, microbial and particulate quality requirements of purified water. Once validated, the acceptability of purified water should be monitored to ensure it continues to be fit for its intended purpose.

4.6 Autoclave application water is intended for use as feed water for autoclaves with heat drying cycles. It is purified to low level of inorganic, organic and particulate impurities that otherwise could contaminate solutions and media in an autoclave. This was previously referred to as Type III water. There is no consensus to specification of this type of water.

4.7 Minimum monitoring requirement includes periodical testing of resistivity and microbiology cultures. The frequency should be enough and the results trended to detect changes and anticipate maintenance problems. In the new water listing Type I and II are the same as CLRW depending on the content requirement and Type III is similar to autoclave and washes water applications.

4.8 Resistivity is an indicator of ionic contamination. It is inversely related to ionic content. The higher this value the better the water quality. It is usually reported in megohm-centimeters (MΩ-cm).

4.9 Check that all containers with water outsourced from external suppliers are tightly closed and the water has no suspended particles in it before signing for it.

4.10 Maintenance of the reservoir:

- 4.10.1 Check overflow tubing for any water weekly;
- 4.10.2 Sanitize overflow tubing with 5% bleach each time the vent filter is changed;
- 4.10.3 Replace overflow tubing if it becomes discoloured;
- 4.10.4 Drain reservoir if not in use for over a week and make sure that the inner wall is dry during storage.

4.11 Water quality is tested annually by sending water sample to the regional laboratory.

4.12 The various water types used in the laboratory should have the following readings:

- 4.12.1 Glassware cleaning
  Restisvety: ≥1.5
  pH: 6.5 – 7.5
  Microbial content: N/A
- 4.12.2 Laboratory analysers
  Restisvety: ≥ 10.5
  pH: 6.7 – 7.3
  Microbial content: ≤ 7 CFU/ml

5. MATERIALS AND EQUIPMENT:

5.1 Water purification system

6. RESPONSIBILITIES:

6.1 The laboratory and blood bank director is responsible for:

- 6.1.1 Ensuring that the laboratory is equipped with required water purification system that at a minimum cost meets the specifications of the purifying system.

6.2 Quality coordinator is responsible for:

- 6.2.1 Ensure that equipment maintenance and calibration are conducted.
- 6.2.2 Providing support for arranging non-routine system repair and reordering of replacement parts.

6.2.3 In cases where the water cannot be processed in the laboratory, reliable suppliers of the required water must be established.
6.2.4 Maintaining the equipment maintenance records.
6.2.5 Ensuring that specifications for laboratory use are checked.
6.2.6 Proper labelling of stored water.

6.3 The Staff is responsible for:
6.3.1 Proper storage of water:
6.3.1.1 Adhering to written equipment operation procedures including preventive maintenance and calibration procedures;
6.3.1.2 Verifying that equipment conforms to specifications prior to use and completing the documentation of such verification.

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 Water Quality – Guidelines., Johnson Hopkins University, Baltimore, USA.
8.2 Pure Water Solutions. www. millipore.com/biosciense.
8.3 Operating and maintenance manual for Riostm and Elix(R) Water Purifications System. Millipore.

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Talal Abdelgawad	Clinical Pathologist		January 01, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 05, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 07, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 12, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 15, 2025