HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Laboratory and Blood Bank Water Types		
Applies To:	All Laboratory and Blood Bank Staff		
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1. PURPOSE:

1.1 To ensure the appropriate use of Reagent Grade to each laboratory section need and maintain its quality.

2. DEFINITONS:

2.1 **Reagent grade water**: Purified water that meets the requirements of laboratory analysis purposes.
2.2 **Resistivity:** The electrical resistance between opposite faces of a one-centimeter cube of a given material at a specified temperature, for water analysis, resistivity is usually reported in megohm (MΩ. cm).
2.3 **CLRW:** Clinical Laboratory Reagent Water
2.4 SRW: Special Reagent Water.

3. POLICY:

3.1 Each section must identify that the reagent grade water used is suitable for the test procedures and should have an adequate supply of the same.
3.2 Water quality parameters must be validated and monitored over time and trends noted to ensure the continuity of meeting specifications (at least annually).

4. PROCEDURE:

4.1 Based on the CLSI guideline "document number C3 - A4", types of reagent grade water can be classified into:
4.2 Clinical Laboratory Reagent Water (CLRW): Water that meets the specification of CLRW should be pure enough to satisfy the requirements of most routine clinical laboratory testing, CLRW is similar to the Type I reagent water defined in earlier editions of this guideline, the CLRW specifications are:

Specifications	Description	CLRW
Microbial Impurities	Total heterotrophic plate count Maximum microbial content	**< 10** CFU/mL 10
Ionic impurities; Resistively	Minimum resistivity (megohm-cm), referenced at 25 °C	**≥ 10** MΩ.cm
Particulate matter	Filter pours size	**0.22** um filter, near or at the output stage

4.3 Special Reagent Water (SRW): When applications require water of different purity than CLRW, the clinical laboratory should specify the SRW needed. The parameters used to specify CLRW should be included in any SRW specifications, but the limits might be different and additional parameters may be added. Some applications that require SRW include trace metal analysis, DNA and RNA testing, endotoxin Test, tissue culture, etc.

4.4 Instrument Feed Water (IFW): Intended for the internal rinsing, dilution, and water bath functions of automated instruments. Use of CLRW for these applications must be confirmed with the manufacturer of a specific instrument, and water meeting the manufacturer's specifications must be used.

4.5 Commercially Bottled Purified Water: that is suitable for certain laboratory procedures, must meet the required specifications for its intended use, water should be packaged in a manner that protects it from environmental contamination or degradation during transportation and storage, containers must be clean to remove surface contamination and sufficiently impermeable to prevent significant external contamination from entering. The container's label must include the lot number, expiry date, and the water specification, and it is preferred to be purchased in small volumes to avoid deterioration due to long storage

4.6 Reagent-grade water used in the laboratory:

4.6.1 The use of reagent-grade water must be identified according to the manufacturer's recommendations and the type of water contaminant that may impact the accuracy of the results. The types of reagent grade water used in laboratory applications are illustrated in the table.

Table 1: Types of reagent-grade water used in the laboratory

Water Grade	Section	Source, specifications	Application
CLRW	- Chemistry - Serology - Immunology - Microbiology	Millipore purification unit serial	- Buffer preparation, diluents, rinsing solution. - Stain preparation - Reagents reconstitution
IFW	Chemistry	Millipore purification	In line feed water to Dimension Beckman and Atellica analyzer
Commercially bottled	Chemistry	Sterile Non pyrogenic distilled water	Controls and calibration preparations
	Immunology	Sterile Non pyrogenic distilled water	Controls and calibration preparations
	Serology	Sterile Non pyrogenic distilled water	Controls and calibration preparations
	Hematology	Sterile Non pyrogenic distilled water	Coagulation reagents, controls preparations
	Microbiology	Sterile Non pyrogenic distilled water	Dilution and reconstitution of reagent and samples

4.7 Water purification systems in the laboratory:

4.7.1 Water purification units that utilize different purification techniques are used to eliminate the level of water contaminates that may interfere with analysis and to ensure that the water dispensed is of consistent quality, the selection of the purification technologies deployed by the

purification unit must be based on the sensitivity of intended applications to specific type of contaminate as illustrated in table 2.

4.7.2 Two units of Millipore AFS16/16D water purification system are used in the Laboratory to produce on-line purified water as IFW and CLRW that meet the specifications for CLRW

4.7.3 The purification systems must be certified as installed to meet the required specification, regular maintenance is carried out by the manufacture and corrective actions must be documented.

4.7.4 Regular monitoring of the water quality parameters and trends must be conducted as described in paragraph

4.7.5 Total Heterotrophic Plate Count (Direct spread plate technique).

4.7.5.1 The determination of total heterotrophic count is an approximation of the viable number of microorganisms present in the system and is expressed in colony forming units (CFU) per millimeter, an indirect spread technique used in the laboratory; the sample is applied directly to the surface of the media and then spread across the surface

4.7.5.1.1 Sample collection:

4.7.5.1.1.1 Water samples should be collected using aseptic technique into sterile specimen containers at each point of use, samples must be collected in a manner that prevents contamination by contact with skin or the environment.

4.7.5.1.1.2 Water samples must be collected from the point of use in a manner consistent with the way it would be drowned normally.

4.7.5.1.1.3 If water is sampled from a port, then the port should be disinfected usually with the hospital approved disinfectant prior to sampling, and the port flushed thoroughly to remove the disinfectant before the water is drowning.

4.7.5.1.1.4 All samples should be gently and thoroughly mixed prior to processing.

4.7.5.1.2 Direct spread plate testing procedure:

4.7.5.1.2.1 Using a sterile pipette, transfer 1 ML of sample onto the surface of one or two agar plate, depending on expected results, but maximum 1 ml per plate. The entire 1 ml of water must be spread on the agar surface.

4.7.5.1.2.2 Spread the sample over the entire agar surface using a sterile "hockey stick" to ensure proper sample distribution.

4.7.5.1.2.3 Incubate the plates at 20 to 38 °C for a minimum of five days. Plates should be inverted to prevent condensation on the agar surface.

4.7.5.1.2.4 Spread plate technique results are valid up to 250 CFU/ plate. Greater than250 CFU represents an overcrowded plate which can inhibit the formation of additional colonies. Results should be questioned if there is considerable clumping of colonies, growth only around the perimeter of the filter, and if duplicate plates are used (i.e., sample split between two plates) and there is significant differences between the two plates.

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4.8 Water purification systems in the laboratory:

4.8.1 Water purification units that utilize different purification techniques are used to eliminate the level of water contaminates that may interfere with analysis and to ensure that the water dispensed is of consistent quality, the selection of the purification technologies deployed by the purification unit must be based on the sensitivity of intended applications to a specific type of contaminate as illustrated in table 2.

4.8.2 Two units of Millipore AFS16/16D water purification system are used in the Laboratory to produce online purified water as IFW and CLRW that meet the specifications for CLRW.

4.8.3 The purification systems must be certified as installed to meet the required specification, regular maintenance is carried out by the manufacturer and corrective actions must be documented

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4.8.5.1.1.2 Water samples must be collected from the point of use in a manner consistent with the way it would be drowned normally

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Table 2: Sensitivity of various clinical assay categories to water contaminants and the technologies used to remove contaminants.

	Ions	Organics	Bacteria	Bacteria by product	Particles
General Chemistry	•		•		
Enzymes	•	•	•		•
Toxicology	•	•	•		
EIA	•	•	•	•	
Trace Elements, TDM	•	•	•	•	
Molecular testing	•	•	•	•	
Diagnostic instruments	•	•	•	•	•
Purification technologies	**RO, EDI, IEX Resins**	**RO, AC, $UV_{185/254}$**	**0.22 um Filter, $UV_{185/254}$ Chemicals**	**UF**	**Filters (0.45, 0.1, 0.22 um; RO, UF)**

RO = Reverse Osmosis, EDI = Electrode ionization, IEX = Ion Exchange Resin, UF = Ultra filtration, AC = Activated Carbon, EIA = Enzyme Immuno Assay

4.9 Quality Control

4.9.1 The QC of water purification units, (CLRW and IFW) is monitored and documented via the "WATER PURIFICATION SYSTEM QC LOG":

4.9.1.1 The displayed resistively (in line reading) must be checked and documented on a daily basis, values must be ≥ 10 MO.cm referenced at 25 °C.

4.9.1.2 A quarterly total Heterotrophic Plate Count must be done and documented, the count must be < 10 CFU/ml

4.9.2 Commercially bottled purified water:

4.9.2.1 Supplied commercially bottled water is certified by the manufacturer, the grade water testing must be carried out and documented in case if the analytical inaccuracy indicated or suspected to be traced to the quality of water by the test QC investigation, for added assurance; random heterotrophic plate count testing for the commercially bottled water will be carried out on a quarterly bases.

4.9.2.2 Proper labeling must indicate the expiry date and the specification of the grade water.

4.9.2.3 Avoid long time storage due to water deterioration.

4.9.2.4 Unaccepted values to be investigated and corrective action should be taken and documented

5. MATERIALS AND EQUIPMENT:

N/A

6. RESPONSIBILITIES:

6.1 All laboratory personnel using water in their test procedures to comply with this policy.

6.2 Supervisors of the sections.

6.3 Laboratory Quality Assurance Officer

7. APPENDICES:

7.1 Validation of label used for blood bag

8. REFERENCES:

8.1 CAP, Laboratory General checklist, Quality of Water and Glassware Washing, Laboratory Accreditation Program, 2009

8.2 CLSI. Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline Fourth Edition, C3-A4, 2008.

8.3 Water for Clinical Chemistry, Stéphane Mabic, Ph.D, Millipore Corporation, Bioscience Division, Saint-Quentin-en-Yvelines. www.millipore.com, 2006.

8.4 AFS-8 and AFS-16, Analyzer Feed Systems, Data sheet, Millipore Corporation, www.millipore.com

9. APPROVALS:

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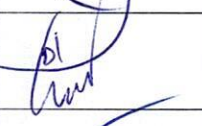
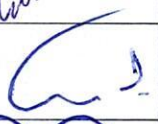
Prepared by:	Dr. Talal Abdelgawad	Clinical Pathologist		May 27, 2025
Reviewed by:	Dr. Kawther M. Abdou	Clinical Pathology Consultant		May 29, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		June 01, 2025
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Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		June 03, 2025
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