



Clinical Practice Standards and Procedures for Dialysis Water Quality: 3: Chemical Analyses of Dialysis Water

Section: HD

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1.0 PRACTICE STANDARD

1.1. Purpose

The Biomedical Technologist or Renal Dialysis Technician who is trained and has demonstrated competency in dialysis water practices will use the procedure outlined in this document to collect dialysis water samples for chemical analyses, and to perform the necessary actions should test results for any of the chemical contaminants exceed its acceptable limits.

1.2. Standards (based on CSA-ISO)

Dialysis water must not contain chemical contaminants at concentrations in excess of those listed in the following table:

Contaminant	Max. Concentration (mg/L)
<i>Contaminants with documented toxicity to haemodialysis</i>	
Aluminum	0.01
Total chlorine	0.1
Copper	0.1
Fluoride	0.2
Lead	0.005
Nitrate (as N)	2
Sulfate	100
Zinc	0.1
<i>Electrolytes normally included in dialysis fluid</i>	
Calcium	2 (0.05 mmol/L)
Magnesium	4 (0.15 mmol/L)
Potassium	8 (0.2 mmol/L)
Sodium	70 (3.0 mmol/L)
<i>Trace elements</i>	
Antimony	0.006
Arsenic	0.005
Barium	0.1
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Mercury	0.0002
Selenium	0.09
Silver	0.005
Thallium	0.002

The quality of the dialysis water must be verified to meet these standards at the time of installation of the water treatment system. Chemical analyses on feed water must be performed to determine the compatibility of the system (or portable RO) with the feed water and the suitability of the RO for providing dialysis water that meets the above standards. Monitoring and testing the chemical concentration levels in the dialysis water should be performed when RO membranes are replaced, when seasonal variations in source water suggest worsening water quality, and at **no less than annual intervals in in-centre units, community clinics, and for portable ROs.**

2.0 DEFINITIONS AND ABBREVIATIONS

<i>Chlorine, combined</i>	Chlorine that is chemically combined, such as chloramine compounds.
<i>Chlorine, free</i>	Dissolved molecular chlorine.
<i>Chlorine, total</i>	Sum of <i>combined chlorine</i> and <i>free chlorine</i> .
<i>Dialysis water</i>	Water that has been treated to meet the requirements of the CSA/ISO standards and which is suitable for use in haemodialysis applications, including the preparation of dialysis fluid.
<i>Feed water</i>	Water supplied to a water treatment system or an individual component of a water treatment system.
<i>Haemodialysis</i>	Form of renal replacement therapy in which waste solutes are removed primarily by diffusion from blood flowing on one side of a membrane into dialysis fluid flowing on the other side.
RO	Reverse osmosis.

Disclaimer: The procedure steps may not depict actual sequence of events. Site-specific considerations may be made when applying the following procedures and protocols.

3.0 EQUIPMENT

- Sampling units (provided by third party testing laboratory; see *Special Considerations* for a list of approved laboratories in BC)
- Gloves

4.0 PROCEDURE

4.1	Collect water samples. <i>Note 1:</i> Samples should be collected as instructed by the third party testing laboratory. <i>Note 2:</i> Samples should always be collected <u>before</u> cleaning/disinfection.
	4.1.1 Feed water samples must be collected from source water, prior to the first water treatment filter.
	4.1.2 Dialysis water samples must be collected from a point in the distal segment of the loop, immediately prior to where water returns to the RO, or immediately prior to where the water re-enters the storage tank, if one is present. For portable ROs, collect the sample from the outlet of the portable RO.
4.2	Send the samples to the third party laboratory for testing and log all incoming results.
4.3	Review the test results.
	4.3.1 If none of the chemical contaminants exceed the acceptable concentration limits, resume routine testing

		Otherwise, take corrective measures (go to step 4.5).
4.4		Perform corrective action (refer to <i>Process Flowchart</i> below).
	4.4.1	If this is the 1 st round of samples, retest immediately (repeat steps 4.1.2 to 4.4.1).
	4.4.2	If this is the 2 nd (or more) round of samples:
	4.4.2.1	Notify the Area Renal Manager, Biomed Risk & Quality, the Biomed Lead Tech, and the Nephrologist.
	4.4.2.2	Assess the RO membranes.
	4.4.2.3	If necessary, shut down the RO, complete a PSLS report, and replace the membranes.
	4.4.2.4	Initiate troubleshooting protocol: <ul style="list-style-type: none"> • Collect and test samples from other parts of the distribution loop (applicable to RO systems only). • Evaluate/correct sample collection technique. • Evaluate/correct compliance with disinfection procedures. • Evaluate/correct water system components. (Verify that everything checks out as per the <i>Dialysis Water Equipment Monitoring</i> clinical standard.)
	4.4.2.5	Retest the system or portable RO (repeat steps 4.1 to 4.4.1).

5.0 DOCUMENTATION CONSIDERATIONS

All chemical analyses test results for feed and dialysis water received from the third party testing laboratory must be documented. These results must be reviewed by the Area Renal Manager, and reviewed and signed off by the Nephrologist **annually**.

6.0 SPECIAL CONSIDERATIONS

- While taking samples, it is important that no contact is made with the inside of the sampling unit.
- The procedure should be done when the system is operating under stable conditions representing normal operation.
- The procedure should not be done within a 2-hour period following a heat clean procedure as the sample may be too warm.
- List of laboratories currently approved by the BC Provincial Health Officer for water testing (alphabetical order):
 - Agrichem Analytical
 - ALS Laboratory Group – Environmental Division – Calgary
 - ALS Laboratory Group – Environmental Division – Vancouver
 - BCCDC PHMRL Environmental Microbiology Laboratory
 - C R D Water Services Laboratory
 - ECO Tech Laboratory Ltd.
 - Exova Canada Inc.
 - IG Micromed Environmental Inc.
 - Maxxam Analytics – Burnaby
 - Maxxam Analytics – Victoria
 - MB Laboratories Ltd.
 - Metro Vancouver Water Laboratory
 - North Island Laboratories
 - Northern Laboratories (2010) Ltd.

7.0 REFERENCES

- CAN/CSA-ISO 13959-11 – Water for haemodialysis and related therapies (Adopted ISO 13959:2009, First edition, 2009-04-15), *Canadian Standards Association*, 2011.

- CAN/CSA-ISO 26722-11 – Water treatment equipment for haemodialysis applications and related therapies (Adopted ISO 26722:2009, First edition, 2009-04-15), *Canadian Standards Association*, 2011.
- Dialysate for hemodialysis (ANSI/AAMI RD52:2004/(R)2010), *Association for the Advancement for Medical Instrumentation*, Arlington (VA), 2009.
- Laboratories Approved by BC Provincial Health Officer for Drinking Water Microbiology Testing, *Enhanced Water Quality Assurance, BC Centre for Disease Control*, Dec. 2010. [Available online: <http://www.phsa.ca/NR/rdonlyres/5B077C99-9015-42AC-943F-32F74E9968B6/0/PHOApprovedLaboratoryList.pdf>]

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NHA Renal Biomedical Technologists and Renal Program Technicians and Managers
FHA Renal Biomedical Technologists and Renal Managers
VIHA Renal Biomedical Technologists and Renal Managers
PHC Renal Biomedical Technologists and Renal Managers

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11.0 APPROVED BY

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12.0 PROCESS FLOWCHART

