South Australian Clinical Practice Guideline

Haemodialysis:

Routine Water Testing and Reverse Osmosis Monitoring

Note:
This guideline provides advice of a general nature. This statewide clinical practice guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The clinical practice guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate, and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements.

Purpose and Scope of Clinical Practice Guideline

The purpose of this guideline is to provide clinicians with information regarding water pre-treatment systems and practices needed to achieve and maintain safe levels in accordance with the ISO 23500-1:2019[1] standard, and applies to registered and enrolled nurses, and haemodialysis technicians who work in haemodialysis units.

The Nurse Unit Manager (or delegate) is responsible for ensuring appropriate testing schedules are implemented in Haemodialysis Units to comply with the procedure and for communicating water quality issues with the Director of Dialysis/ Medical Lead or on call medical consultant after hours.

The Director of Dialysis/ Medical Lead is accountable for ensuring water quality standards are met.

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Compliance

- Compliance will be monitored by the Haemodialysis Unit Nurse Unit Manager.
- Patient related water incidents will be reported via the Safety Learning System.
- Water quality audits against guideline will be performed every 6 months.

Summary of Practice Recommendations

- Bacterial and endotoxin water testing is designed to help identify and prevent bacterial proliferation in the water treatment system.
- Monitoring levels of bacteria and endotoxin helps provide evidence that the disinfection program of the Reverse Osmosis unit is effective in suppressing bacterial growth and endotoxin and aids in maintaining patient safety.

Abbreviations

BME	Biomedical Engineering
CFU	Colony Forming Units
EU	Endotoxin Units
HDF	Haemodiafiltration
ISO	International Organization for Standardization
L	Litre(s)
LAL	Limulus Amoebocyte Lysate
LHN	Local Health Network
mg	Milligram(s)
mL	Millilitre(s)
mmol	Millimole(s)
RO	Reverse Osmosis
TGEA	Tryptone Glucose Yeast Extract Agar
TGO	Therapeutic Goods Orders
uS/cm	micro-Siemens per centimetre

Definitions

Bacteria	Single celled micro-organisms which can exist either as independent free-living organisms or as parasites.
Colony forming Units	Ability of each living bacterial cell present in water to grow into a discrete colony
Haemodialysis Water	Product water from reverse osmosis unit. Also known as permeate.
Endotoxin	Gram-negative bacterial wall fragments that are regarded as the major pyrogenic contaminants in water and haemodialysis fluid.
Limulus Amoebocyte Lysate assay	A specific test used for the detection of endotoxins
Online Machines	Haemodialysis Machines (e.g. Fresenius) produce ultra-pure haemodialysis fluid which is used for priming and reinfusion of the blood circuit for conventional haemodialysis as well as Haemodiafiltration.
Total Bacterial Counts	Determines the number of colony forming Units and is expressed per mL of water
Ultrapure haemodialysis fluid	Water filtered through endotoxin retentive filters.

Testing of Water

Testing of haemodialysis machines for bacterial growth and endotoxins is not required if the haemodialysis machine fluid pathway is fitted with an appropriate endotoxin retentive filter, validated by the manufacturer and operated and monitored according to the manufacturer instructions.

The presence of bacteria can be detected in 2 ways:

- Total Bacterial Count expressed in Colony Forming Units (CFU)/mL
- Endotoxin testing by Limulus Amebocyte Lysate (LAL) test expressed in Endotoxin units (EU)/mL.

Total Bacterial Counts and Endotoxin testing

Haemodialysis water from central and portable Reverse Osmosis (RO) Units.

Total bacterial count testing

- Corrective measures and retesting should be initiated for a total viable microbial count **>= 50 CFU/mL**.
- If RO water returned from distribution loop (water from RO) contains a total viable microbial count **>= 100 CFU/mL** it cannot be used for haemodialysis.

Endotoxin testing

- Corrective measures and retesting should be initiated at an endotoxin concentration of **0.125 EU/mL**.
- Endotoxin concentration must be lower than 0.25 EU/mL in RO water returned from distribution loop (water from RO)

Frequency of testing

Note: *Haemodialysis units located in regional areas may have local agreements for testing. This procedure is based upon ISO 23500-1 guidelines.*

Central and portable Reverse Osmosis Units

- Total bacterial counts, endotoxin concentration (LAL) and chemical analysis of product water (from RO) must be completed upon installation. Total bacterial counts (CFU), endotoxin concentration (LAL) must be monitored monthly to ensure the water quality provided for patient treatment.
- More frequent monitoring may be required if an upward trend of bacterial testing results indicate that maximum allowable levels may eventually be exceeded. It is the responsibility of the Nurse Unit Manager (or delegate) to monitor results and determine if increase in frequency of testing is required.
- Each Local Health Network should develop their own escalation process as per LHN Business continuity plans.

Online machines - Ultrapure haemodialysis fluid

Statement: ISO 23500:2019
Tests for bacterial growth and endotoxins are not required if the haemodialysis machine is fitted with an appropriate capacity bacteria retentive and endotoxin-retentive filter validated by the manufacturer and operated and monitored according to the manufacturer's instructions.

Test CFUs and LALs on installation/commissioning. No ongoing testing is required as per ISO 23500:2019.

Acceptable levels of chlorine and chloramine

As testing of total chlorine is usually performed, the limit for total chlorine should be 0.1 mg/L.

Carbon shall be replaced on a 12 monthly basis or earlier if trending of test results indicates an increasing level of total chlorine concentrations are experienced.

Each unit must have a policy and decision-making tree/ flow chart that outlines the strategy for management of total chlorine levels that exceed 0.1 mg/L.
See Appendix 2 – Surveillance of carbon media.

Action when high test results are obtained

Central and portable RO

- If CFUs and LALs exceed allowable levels the tests should be repeated following the completion of the corrective measures.

a. *Corrective measures and retesting should be initiated for a total viable microbial count* ***>= 50 CFU/mL****.*

b. *If RO water returned from distribution loop (water from RO) contains a total viable microbial count* ***>= 100 CFU/mL*** *it cannot be used for haemodialysis.*
   - The Nurse Unit Manager (or delegate) is responsible for communicating water quality issues with the Director of Dialysis/ Medical Lead and Nurse Lead/Nursing Director, or the on call medical consultant after hours.
   - If maximum allowable levels of bacteria have been reached for haemodialysis water, corrective measures should be put in place (such as disinfection of the loop, chemical disinfect of RO) to reduce concentrations.

A risk management approach must be used with analysis of risk and controls implemented to ensure patient safety is maintained, which is reported to the Nurse Lead/Nursing Director and Director of Dialysis/ Medical Lead.

Chemical Contaminant Testing

- Contaminant testing frequency will be conducted annually as prescribed in Appendix 1.
- In the case of South Australia, we use quality potable water that meets Australian drinking water guidelines. The water is processed with a Therapeutic Goods Administration registered RO that is specifically designed to produce water for haemodialysis.
- The haemodialysis water will be observed and monitored by nursing staff using conductivity of <25 uS/cm.
- Rejection rates must be greater than 90%. If the rejection rate is 90% or less, the service provider who services your RO must be contacted before haemodialysis treatment commences.

Home Haemodialysis

Statement

The microbiological quality of the haemodialysis fluid should be analysed using cultures and endotoxin measurements. If the haemodialysis fluid meets the recommendations of ISO 23500-5, then the haemodialysis water (product water from RO) feeding the haemodialysis machine and the bicarbonate concentrate can be assumed to meet appropriate requirements." ISO 23500-1.

If the water source is from main supplies and meets the Australian water drinking guidelines the following will be implemented:

- Portable RO: Total bacterial counts (CFU), endotoxin concentration (LAL) and chemical analysis of haemodialysis water (from RO) must be completed upon installation.
- Home haemodialysis machines fitted with endotoxin retentive filter: (Ultrapure haemodialysis fluid) test CFUs and LALs on installation/ commissioning.

If the water source is not from mains water supplies, such as a rainwater tank, yearly chemical analysis from portable RO (haemodialysis water) is recommended. Liaise with the service provider who services your RO for advice.

Collection and sampling of Haemodialysis Water from Central RO

Collection of haemodialysis water from central RO for Total Bacterial count (CFU) and endotoxin testing (LAL)

Monthly

Note: Specimens should be assayed within 30 minutes**. Specimens kept outside these time frames must be refrigerated. Samples must be stored at 5°C and assayed within 24 hours.**

Haemodialysis: Routine Water Testing and Reverse Osmosis Monitoring

Haemodialysis units located in regional areas may have local agreements for testing, including onsite LAL and freezing CFU water samples for transport. This procedure is based upon ISO 23500-1 guidelines.

Equipment

- Refrigerator for specimen storage
- 2 x yellow sterile specimen containers
- 70% Isopropyl Alcohol wipes
- Bucket
- Pathology Form

Process

- Perform hand hygiene
- Identify product water tap or product water source, for Central RO
- Using an alcohol wipe thoroughly clean the outside of the tap for 30 seconds and allow to dry
- Run 2 litres of water into a bucket and discard.
- Avoiding contamination, slowly open the tap and fill each yellow specimen container to half full.
- Replace lid immediately being careful not to contaminate the inside of the specimen container.
- Label with the appropriate identification labels (i.e., product water and mark as URGENT)
- If sample not sent to SA Pathology immediately, it would require refrigeration
- Send the labelled specimen container with the appropriate lab form to SA Pathology - FOOD and ENVIRONMENTAL LAB.

Collection of Haemodialysis Water (from portable RO) for Total Bacterial count (CFU) and endotoxin I (LAL)

Monthly

Note: Specimens should be assayed within 30 minutes**. Specimens kept outside these time frames must be refrigerated. Samples must be stored at 5°C and assayed within 24 hours.**

Portable RO Equipment:

- Water sampling connector
- 2 x yellow specimen containers
- Bucket
- SA Pathology forms
- 70% Isopropyl Alcohol wipes

Process

- Ensure RO is connected to main water tap and drain and turned on
- Run the RO for a minimum of 15 minutes to flush the RO
- Perform Hand Hygiene
- Wipe the sample port with an alcohol wipe for 1 minute and allow to dry
- Run 2 litres of water into a bucket and discard.
- To avoid contamination, slowly open the tap and fill each yellow specimen container to half full.
- Replace lid immediately being careful not to contaminate the inside of the specimen container.
- Label with the appropriate identification labels i.e., RO water and mark as URGENT
- If sample not sent to pathology immediately, it would require refrigeration
- Send the labelled specimen container with the appropriate lab form to SA Pathology - FOOD and ENVIRONMENTAL LAB.

Risk factors

As per Annex A ISO23500-1-2019. It has long been known that chemical and microbiological contamination of haemodialysis fluid places haemodialysis patients at risk of acute and chronic adverse events.

Appendix 1: Frequency of water testing and monitoring

Reverse Osmosis Units

Reverse Osmosis Unit				
Monitoring	**Test**	**Sample**	**Frequency**	**Limit**
Haemodialysis water Conductivity	Visual Inspection	Displayed haemodialysis water conductivity <25 uS/cm	Daily before first Haemodialys is treatment commenced	If conductivity greater than 25 uS/cm or rejection rate <90% inform service provider who maintains RO
Rejection Rate	Visual Inspection	Displayed rejection rate should be >90%		

Haemodialysis Water – Reverse Osmosis Unit					
Monitoring	**Action Level**	**Limit level**	**Frequency**	**Recommended Testing Method**	**Comment**
Viable counts	50 CFU/mL	100 CFU/mL	Monthly	As per standard laboratory testing methods	Ideally for maximum microbial recovery, incubation temperatures 17°C to 23°C for 168 hours with TGEA or R2A Plate
Endotoxins	0.125 EU/mL	0.25 EU/mL	Monthly	Limulus Amebocyte Lysate (LAL)	

Haemodialysis Water-Reverse Osmosis Unit				
Monitoring	**Test**	**Sample**	**Frequency**	**Limit**
Contaminants with documented toxicity in HD	Aluminum	Post RO Water	Annually	0.01 mg/L
	Copper	Post RO Water	Annually	0.1 mg/L
	Fluoride	Post RO Water	Annually	0.2 mg/L
	Lead	Post RO Water	Annually	0.005 mg/L
	Nitrate (as Nitrogen)	Post RO Water	Annually	2.0 mg/L
	Sulphate	Post RO Water	Annually	50 mg/L
	Zinc	Post RO Water	Annually	0.1 mg/L

Haemodialysis Water-Reverse Osmosis Unit (continued)				
Monitoring	**Test**	**Sample**	**Frequency**	**Limit**
Electrolytes	Calcium	Post RO Water	Annually	2 mg/L
	Magnesium	Post RO Water	Annually	2 mg/L
	Potassium	Post RO Water	Annually	2 mg/L
	Sodium	Post RO Water	Annually	50 mg/L

Haemodialysis Water-Reverse Osmosis Unit				
Monitoring	**Test**	**Sample**	**Frequency**	**Limit mg/L**
Maximum allowable levels of trace elements in Haemodialysis water	Antimony	Post RO Haemodialysis water	Annually	0.006 mg/L
	Arsenic	Post RO Haemodialysis water	Annually	0.005 mg/L
	Barium	Post RO Haemodialysis water	Annually	0.1 mg/L
	Beryllium	Post RO Haemodialysis water	Annually	0.0004 mg/L
	Cadmium	Post RO Haemodialysis water	Annually	0.001 mg/L
	Chromium	Post RO Haemodialysis water	Annually	0.014 mg/L
	Mercury	Post RO Haemodialysis water	Annually	0.0002 mg/L
	Selenium	Post RO Haemodialysis water	Annually	0.09 mg/L
	Silver	Post RO Haemodialysis water	Annually	0.005 mg/L
	Thallium	Post RO Haemodialysis water	Annually	0.002 mg/L

Appendix 2: Surveillance of carbon media

If chlorine is used in the feed water, the performance of carbon beds is monitored by measuring the total chlorine concentration in the water exiting the carbon bed or exiting the first carbon bed when a series-connected pair of beds is used. The total chlorine level should not exceed 0,1 mg/L.

Testing for total chlorine can be accomplished using the N,N-diethyl-p-phenylenediamine (DPD)-based test kits, dip-and-read test strips based on Michler's thioketone (MTK or TMK), or other methods where comparable sensitivity and specificity can be demonstrated. Online monitors can also be used to measure total chlorine concentrations. If an online monitor is used, it should be used and maintained in accordance with the manufacturer's instructions. Whichever test system is used, it should have sufficient sensitivity and specificity to resolve the maximum levels described in Table 1.

When offline tests are used, testing for total chlorine should be performed at the beginning of each treatment day prior to the patient's initiating treatment. Where chloramine is used to disinfect the potable water supply at a level of 1 mg/l or more, testing should be repeated prior to the beginning of each patient shift.

More frequent surveillance could be appropriate during temporary operation with a single carbon bed, which can occur following breakthrough of the first bed. In such instances, testing is performed on water exiting the second carbon bed in a series-connected pair.

The decision to change the frequency of surveillance (based local policy) should be based on the past performance of the system and on whether changes in feed-water quality have occurred.

The system should be flushed for a minimum flush time of 15 minutes to ensure that water sampled is representative of the water to be used for treatment. Sufficient flushing is necessary to ensure that sampled water has not been resident in the removal system between treatments, such that it would under-represent the chloramine level that would be delivered during normal operation.

The analysis should be performed onsite since total chlorine levels will decrease if the sample is note assayed promptly.

Results of surveillance should be recorded on a log sheet.

Table 1: Maximum allowable levels of toxic chemicals and haemodialysis fluid electrolytes in haemodialysis water [a, b]

Contaminant	Maximum Concentration mg/l[c]
Contaminants with documented toxicity in haemodialysis	
Aluminium	0,01
Total chlorine[d]	0,1
Copper	0,1
Fluoride	0,2
Lead	0,005
Nitrate (as N)	2
Sulphate	50
Zinc	0,1
Electrolytes normally included in haemodialysis fluid per ISO 23500-3	
Calcium	2 (0,05 mmol/1)
Magnesium	4 (0,15 mmol/1)
Potassium	8 (0,02 mmol/1)
Sodium	70 (3,0 mmol/1)

a. A haemodialysis facility Director of Dialysis/ Medical Lead has the ultimate responsibility for ensuring the quality of haemodialysis water.

b. The reader is cautioned to refer to the latest version of ISO 23500-3 to ensure that there have been no changes to this table.

c. Unless otherwise noted.

d. When chloring is added to water, some of the chlorine reacts with organic materials and metals in the water and is not available for disinfection (the Chlorine demand of the water). The remaining chlorine is the total chlorine and is the sum of free chlorine or non-bound chlorine and combined chlorine.

There is no direct method for the measurement of chloramine. It is generally established by measuring total and free chlorine concentrations and calculating the difference. When total chlorine tests are used as a single analysis the maximum level for both chlorine and chloramine shall not exceed 0.1 mg/1. Since there is no distinction between chlorine and chloramine, this safely assumes that all chlorine present is chloramine.

Source: ISO 23500-1:2019[E]

References

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