1.0 Title
Renal Haemodialysis: Dialysate and Water Sample Collection for Microbiological Testing and Replacement of Filters on Portable Reverse Osmosis (RO) Units

2.0 Purpose
The purpose of this procedure is to provide guidance for the collection of treated water and dialysate for testing of microbiological matter, specifically Colony Forming Units (CFU) and Endotoxin counts (EU).

This procedure covers the collection of dialysate samples from the haemodialysis machine, water samples from the ring main and portable reverse osmosis (RO) and the replacement of portable RO units.

Failure to ensure adequate water quality may have dire consequences for patient safety and welfare. Patients undergoing haemodialysis may show signs and symptoms related to water contamination, which can lead to patient injury or death. (ACI Renal Network – Water for dialysis: A guide for in-centre, satellite and home haemodialysis in NSW 2018)

This procedure is guided by the NSW Agency for Clinical Innovation (ACI) document titled “Water for Dialysis - A Guide for In-centre Satellite and Home Haemodialysis in NSW.” The Standards in this document are drawn from the International Standards Organisation (ISO) current at the time of release of this document (26 May 2016).


Schedule:
- The water sampling and microbiology testing of all haemodialysis machines are initially done monthly after install for 3 months, progressing to a maximum 3 monthly intervals.
- The ring main loop(s) and portable RO units are tested monthly.
- Rotate spare machines on/off treatment floor.
- Any haemodialysis machine that is faulty and awaiting technical assessment cannot be tested until it has been returned to service by Fresenius Technician.
- The Renal Unit NUM is responsible for assigning trained RN/EN to
perform water sampling and overseeing the Renal Water Testing Logbook.

3.0 Procedure

3.1 Equipment for sampling dialysate, treated water from the ring main and portable reverse osmosis (RO) units

- PPE – Apron, non-sterile gloves.
- Alcohol based hand rub (AHBR).
- Clean Trolley.
- Transport container - Esky with cooling packs or ice.
- 2 x yellow-top specimen jar and 1 x blue/black-top endotoxin tube each per number of serviceable haemodialysis machines, ring main loop and R.O units to be tested, and pathology specimen bags. Please note: LBH laboratory requires 100mls dialysate sample required for CFU’s hence 2 yellow top jars and 3 x50ml syringes.
- 3 x 50ml luer lock syringes per number of dialysis machines to be tested.
- Dressing pack, 70% alcohol wipes OR chlorhexidine 2% in alcohol 70% solution plus 20ml syringes if irrigating sample port with solution.
- Labels for each sample from machines, ring main(s), Portable RO units.
- Completed pathology request forms x 1 for each dialysis machine, potable RO unit or ring main sample.
- Haemodialysis machine setup with Dialysate Part A, BiBag, bloodlines and dialyser.

3.1.1 Equipment required for portable RO sampling and filter replacement

- Water collecting hose with swaze lock connector and inline tap pre disinfect internally with chlorhexidine 2% for portable RO units.
- Clean household bucket 13L capacity for RO rinsing.
- Bottle brush for cleaning Portable RO filter housings.
- 5-micron water filters (pre carbon tank) for each RO.
- 1-micron water filters (post carbon tank) for each RO.

3.2 Sending Samples to Microbiology

- Inform microbiology contact personnel of the number of sterile jars and endotoxin tubes and arrange transport of sample to pathology lab.
- Sample must be tested within 30 minutes of collection, or be immediately stored at a temperature between 1 – 5 degrees Celsius to be assayed within 24 hours.

3.3 DIALYSATE COLLECTION: Haemodialysis machine

- Commence T1 test and line the Haemodialysis machine if intending to use for treatment.
- When T1 test is complete, perform hand hygiene, connect Safe-Line to On-Line pump and blood lines and connect dialysate connectors to the dialyser. Start prime.
- Samples can be collected pre-treatment or during treatment.
- Increase dialysate flow rate to 1000mls/hr if collecting sample pre-treatment.
• Do not adjust dialysate flow rate if patient on treatment.
• Don PPE and perform hand hygiene.
• After dialysis lines are primed, open dressing pack and prepare 2 x yellow-top sample jar (for CFU) and 1 x blue/ black-top tube (for endotoxin) onto edge of dressing pack.
• Clean surrounds and inside dialysate access port with chlorhexidine 2% in alcohol 70% by syringe irrigation, or use chlorhexidine / alcohol 70% swabs, and allow 2 minutes drying time.
• Connect a 50ml syringe to dialysate port. Press and hold down the lever and withdraw 50ml dialysate and discard syringe. (If unable to withdraw fluid inject 5cc of air into the sampling valve to release airlock in order to withdraw fluid).
• Perform hand hygiene. Attach new 50ml syringe and withdraw approximately 50ml dialysate. Protect key parts using non touch technique. Take care not to touch inside of yellow lid with hands or syringe, remove yellow lid from containers and fill each with 50ml of dialysate. Add remaining into black top tube. Securely close yellow and black lids and apply labels to each container.
• Label yellow top jar with machine number, test: CFU, & sample type DIALYSATE.
• Label blue/black top tube with machine number, test: ENDOTOXIN & sample type DIALYSATE.
• Add date and time to pathology form, include site, location and collector details as per site specific requirements.
• Place samples in esky with cooling packs or ice and continue around machines until all scheduled haemodialysis machines are tested.

3.4 WATER COLLECTION: Ring main loop(s).
• Open access port(s) on ring main(s) and run approximately 7litres of water into a clean household bucket to flush.
• Perform Hand Hygiene and prepare 2 x yellow-top jars and 1 x blue/black top tube for each loop.
• Turn water flow down, and using non touch technique to protect key parts, collect 100 mls clean catch water samples in 2 yellow-top jars for CFU test and blue/ black top jar for ENDOTOXIN test.
• Close access ports on Ring Main.
• Label yellow top jars with loop number, test: CFU, & sample(s): RING MAIN LOOP WATER (#1 or #2).
• Label blue/ black top tube with loop number, test: ENDOTOXIN, & sample(s): RING MAIN LOOP WATER (#1 or #2).
• Add date and time to pathology form, include site, location and collector details as per site specific requirements.
• Place samples into esky with cooling packs or ice ensuring label on blue/ black-top tubes and yellow-top jars matches label on respective pathology forms.

3.5 WATER COLLECTION: Portable RO's
• Scroll through the menu to “on” and press ↵ Key.
• Attach water collecting hose to the swaze lock labelled “Water to
Machine” on the portable RO.
- Scroll through the menu to “Standby On” and press ← Key.
- Run out 60 seconds worth of RO permeate water into a clean household bucket to flush the water sample hose before utilising aseptic non touch technique to collect a clean catch RO permeate water sample in 2 yellow-top jars (100mls sample required by lab) and a black top tube. Repeat for each RO.
- Label **yellow top jars** with machine number, test: CFU, & sample(s): PORTABLE RO WATER.
- Label **blue/ black top tubes** with machine number, test: ENDOTOXIN, & sample(s): PORTABLE RO WATER. Add date and time to form, include Site, Location and collector details as per usual pathology request.
- Place samples into esky with cooling packs or ice ensuring label on blue/ black-top tubes and yellow-top jars matches label on respective pathology forms.

### 3.6 PROCEDURE FOR REPLACING FILTERS ON PORTABLE RO’s
- Turn off water supply at wall tap. When machine flashes ‘No Water’ message, turn off power to RO at the wall power switch.
- Using the plastic housing wrench, undo one filter housing at a time on RO Trolley.
- Discard old filter and clean and rinse filter housing using a bottle brush to assist.
- Replace with new filter taking care to ensure correct size filter is used.
- Close housing, but not too tightly.
- When both filters are changed, turn on water at wall tap and scroll through the menu to “Manual Rinse” and press ← Key.
- Observe filter housings for any leaks. Tighten housing if leaks occur.
- Allow manual rinse to run its programmed duration to flush new filters.
- Document in RO workbook that the RO’s have been Run / Rinsed, water tested, & filters changed.

### 3.7 After completion, clean and restock trolley and prepare forms/labels for next month’s collection.

### 3.8 Documentation/Recording of results:
Follow up results when available (LAL 24hrs, CFU 72 hours). Refer to Section 5.2 for acceptable results ranges and actions for out of range results.

Results are recorded on CFU and LAL Testing Schedule Logbook (example Appendix 1)

### 4.0 Required Knowledge and Assessment to Perform this Procedure
All trained dialysis staff are required to have:
- a fundamental understanding of water treatment for haemodialysis.
- Competence in operating Fresenius 4008, 5008 machines.
Competence in operating portable RO AquaUNO.
Hand Hygiene.
Aseptic non touch technique.
Electronic Medical record training.

Renal Unit NUM is to nominate dialysis trained RN /EN staff member(s) to collect and dispatch samples as outlined above.
Nominated Staff member(s) is to have access to Auslab for results.
Nominated staff member(s) is to report results actions to NUM.

5.0 Monitoring and Evaluation.
- Scheduling of machines to be tested is maintained as per electronic documentation (excel spreadsheet on site specific drives).
- Documentation of water samples taken from the loop, machines tested, dates, results and actions are required to be maintained within site specific documentation.
- Audit compliance with training, sampling and documentation.
- Audit 5 Moments of Hand Hygiene (MHH).
- Local Incident Information Management System (IIMS) data.

5.1 Trouble shooting test results:
- Evaluate correct sample technique.
- Evaluate correct water system components.
- Evaluate/replace equipment.

5.2 REVIEWING RESULTS AND ACTIONS (Standard: ISO 13959-2014)
Online substitution fluid, known as ultrapure, is produced by 5008 HDF machines and is used for both priming the extra-corporeal circuit and will enter the patient’s blood stream in HDF treatment. This fluid must be sterile and free of pyrogens. Dialysate collected from 5008 HDF machines used in-centre will be compared to Ultrapure Standards as follows:

### Dialysate from 5008 HDF machines (in-centre)

<table>
<thead>
<tr>
<th>MICROORGANISMS (CFU/ml) and ENDOTOXINS (EU/ml)</th>
<th>Level</th>
<th>Actions When achieved, fluid of a suitable quality is to be used for high-flux dialysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFU/ml</td>
<td>&gt;0.1</td>
<td><strong>Remove machine from service.</strong> Attach a copy of the pathology results over the item’s control panel together with a Fault Notification signage. Bleach clean and retest. Inform NUM, Medical Director and Fresenius Technician.</td>
</tr>
<tr>
<td>EU/ml</td>
<td>&gt;0.03</td>
<td></td>
</tr>
</tbody>
</table>
### Dialysate from HD Machines

<table>
<thead>
<tr>
<th>MICROORGANISMS and ENDOTOXINS</th>
<th>Level</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFU/ml maximum</td>
<td>&gt;100</td>
<td>Remove machine from service. Attach a copy of the pathology results over the item’s control panel together with a Fault Notification signage. Bleach clean and retest. Inform NUM, Medical Director and Fresenius Technician. Await results and <strong>return to service if &lt;50 CFU/ml and &lt;0.12</strong> Schedule monthly testing for 3 months.</td>
</tr>
<tr>
<td>EU/ml maximum</td>
<td>&gt;0.25</td>
<td>Remove machine from service. Attach a copy of the pathology results over the item’s control panel together with a Fault Notification signage. Bleach clean and retest. Inform NUM, Medical Director and Fresenius Technician. Await results and <strong>return to service if &lt;50 CFU/ml and &lt;0.12</strong> Schedule monthly testing for 3 months.</td>
</tr>
</tbody>
</table>

| CFU/ml action level          | >50   | Remove machine from floor. Bleach clean and retest. Inform NUM and Fresenius technician. Do not use for HDF until results reviewed. Await results and **return to service if <50 CFU/ml and <0.12** Schedule monthly testing for 3 months. |
| EU/ml action level           | >0.12 | Remove machine from floor. Bleach clean and retest. Inform NUM and Fresenius technician. Do not use for HDF until results reviewed. Await results and **return to service if <50 CFU/ml and <0.12** Schedule monthly testing for 3 months. |

| CFU/ml safe level            | <50   | Resume/ continue operation |
| EU/ml safe level             | <0.12 | Retest monthly |

### Ring main water

<table>
<thead>
<tr>
<th>MICROORGANISMS and ENDOTOXINS</th>
<th>Level</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFU/ml maximum</td>
<td>100</td>
<td><strong>Suspend operations.</strong> Inform Medical Director, NUM and Fresenius Technician Chemical disinfection of the loop may be required by technician or maintenance. Retest. Await results and <strong>return to service if &lt;50 CFU/ml.</strong></td>
</tr>
<tr>
<td>EU/ml maximum</td>
<td>0.25</td>
<td><strong>Suspend operations.</strong> Inform Medical Director, NUM and Fresenius Technician Chemical disinfection of the loop may be required by technician or maintenance. Retest. Await results and <strong>return to service if &lt;50 CFU/ml.</strong></td>
</tr>
</tbody>
</table>

| CFU/ml action level          | 50    | Inform NUM and Fresenius Technician. Chemical disinfection may be required by technician or maintenance. Retest. Await results and **return to service if <50 CFU/ml.** |
| EU/ml action level           | 0.12  | Inform NUM and Fresenius Technician. Chemical disinfection may be required by technician or maintenance. Retest. Await results and **return to service if <50 CFU/ml.** |

| CFU/ml safe level            | <50   | Resume/ continue operation |
| EU/ml safe level             | <0.12 | Retest monthly |

### Portable RO water

<table>
<thead>
<tr>
<th>MICROORGANISMS and ENDOTOXINS</th>
<th>Level</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFU/ml maximum</td>
<td>&gt;100</td>
<td><strong>Remove from service.</strong> Inform Medical Director, NUM and Fresenius Technician Dialox disinfection required by technician or Home HD staff. Retest. <strong>Home Haemodialysis:</strong> Following disinfection, portable RO can be used for HD treatment but not HDF – place sign on RO. <strong>In centre:</strong> Await results and <strong>return to service if &lt;50 CFU/ml.</strong></td>
</tr>
<tr>
<td>EU/ml maximum</td>
<td>&gt;0.25</td>
<td><strong>Remove from service.</strong> Inform Medical Director, NUM and Fresenius Technician Dialox disinfection required by technician or Home HD staff. Retest. <strong>Home Haemodialysis:</strong> Following disinfection, portable RO can be used for HD treatment but not HDF – place sign on RO. <strong>In centre:</strong> Await results and <strong>return to service if &lt;50 CFU/ml.</strong></td>
</tr>
</tbody>
</table>

<p>| CFU/ml action level          | &gt;50   | <strong>Remove from service.</strong> Inform Medical Director, NUM and Fresenius Technician Dialox disinfection required by technician or Home HD staff. Retest. <strong>Home Haemodialysis:</strong> Following disinfection, portable RO can be used for HD treatment but not HDF – place sign on RO. <strong>In centre:</strong> Await results and <strong>return to service if &lt;50 CFU/ml.</strong> |
| EU/ml action level           | &gt;0.12 | <strong>Remove from service.</strong> Inform Medical Director, NUM and Fresenius Technician Dialox disinfection required by technician or Home HD staff. Retest. <strong>Home Haemodialysis:</strong> Following disinfection, portable RO can be used for HD treatment but not HDF – place sign on RO. <strong>In centre:</strong> Await results and <strong>return to service if &lt;50 CFU/ml.</strong> |</p>
<table>
<thead>
<tr>
<th></th>
<th><strong>Home Haemodialysis:</strong> Following disinfection, portable RO can be used for HD treatment but not HDF – place sign on RO. <strong>In centre:</strong> Await results and return to service if &lt;50 CFU/ml.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFU/ml safe level</td>
<td>&lt;50</td>
</tr>
<tr>
<td>EU/ml safe level</td>
<td>&lt;0.12</td>
</tr>
<tr>
<td></td>
<td>Resume/ continue operation</td>
</tr>
<tr>
<td></td>
<td>Retest monthly</td>
</tr>
</tbody>
</table>

### 6.0 Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bibag (Bicarbonate)</td>
<td>Concentrated preparation of sodium bicarbonate that, when diluted with dialysis water and acid concentrate, makes dialysis fluid used for dialysis</td>
</tr>
<tr>
<td>Bleach</td>
<td>Chemical used to disinfect Haemodialysis machines</td>
</tr>
<tr>
<td>Blood lines and dialyser</td>
<td>Lines and filter required to set up machine for Haemodialysis treatment</td>
</tr>
<tr>
<td>Chemical disinfection</td>
<td>Substance used to disinfect the Ring Main Loop</td>
</tr>
<tr>
<td>Colony Forming Units (CFU)</td>
<td>Measure of bacterial or fungal cell numbers that theoretically arise from a single cell or group of cells when grown on a solid media</td>
</tr>
<tr>
<td>Dialox</td>
<td>Chemical used to disinfect Portable RO machines</td>
</tr>
<tr>
<td>Dialysate part A (Dialysis concentrate)</td>
<td>Bottle of fluid containing electrolytes and usually buffer and glucose, which is intended to exchange solutes with blood during haemodialysis</td>
</tr>
<tr>
<td>Dialysate</td>
<td>Mixture of post RO treated water and dialysate fluid</td>
</tr>
<tr>
<td>Endotoxin Count (EU)</td>
<td>Major component of the outer cell wall of gram negative bacteria that produce an inflammatory host response</td>
</tr>
<tr>
<td>Haemodialysis</td>
<td>Form of renal replacement therapy in which waste solutes are removed primarily by diffusion from blood flowing from one side of a membrane into dialysis fluid flowing on the other side</td>
</tr>
<tr>
<td>Haemodialysis Machine</td>
<td>4008S and 5008 series Haemodialysis machines</td>
</tr>
<tr>
<td>Housing wrench</td>
<td>Tool used to loosen filters from RO machine</td>
</tr>
<tr>
<td>Microbiological</td>
<td>Contamination with any form of microorganism(e.g. bacteria, yeast, fungi and algae)</td>
</tr>
<tr>
<td>Micron Filter</td>
<td>Specifically designed filter with small pore size to reduce the level of bacteria in a fluid system</td>
</tr>
<tr>
<td>Permeate</td>
<td>Treated or purified water</td>
</tr>
<tr>
<td>Reverse Osmosis (RO)</td>
<td>The process of forcing water from one side of a semi-permeable membrane to the other, producing purified water by leaving behind the dissolved solids and organic particles</td>
</tr>
<tr>
<td>Ring main water</td>
<td>Water that has been treated to minimum International Standards for use in haemodialysis applications which circulates throughout the Renal Unit</td>
</tr>
<tr>
<td>Swaze lock connector</td>
<td>Specific connection for access to some water treatment systems</td>
</tr>
</tbody>
</table>
### Ultrapure fluid (infusate)

Highly purified dialysis fluid used as a feed solution to create fluid for infusion directly into the blood.

### 7.0 References

- Fresenius Medical Care 4008, 5008: Haemodialysis system operating instructions.
- Fresenius Medical Care: reverse osmosis AquaUNO operating instructions.
- Fresenius Medical Care: Monitoring of reverse osmosis systems and routine water testing January 2013.
- Lismore Pathology: Glenn Hawkins - Senior Scientist | **Pathology North – Lismore**.
- Nurse Educator network (NEN) on line package “Water Quality for Haemodialysis.
- PD2017_013 **Infection Prevention and Control Policy**.
- NC-NNSW-POL-7685-16 **LHD Infection Prevention and Control Program**.
- NC-NNSW-PRO-7549-15 **Aseptic Technique**.

### 8.0 Appendices

#### Appendix 1:

Example of CFU and LAL Testing Schedule Logbook.
APPENDIX 1: Example of CFU and LAL Testing Schedule Logbook

BDH HAEMODIALYSIS MACHINE CFU and ENDOTOXIN TESTING SCHEDULE

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<thead>
<tr>
<th>Machine Serial Number</th>
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<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
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</table>

(To note red corners are comments that using the live Excel sheet would provide more information about issues & testing)
### 9.0 NNSW LHD Clinical Procedure Cover Sheet

<table>
<thead>
<tr>
<th>COVER SHEET</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NNSW Local Health District CLINICAL Policy Framework</td>
<td><img src="image" alt="NSW Health" /> Northern NSW Local Health District</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>Renal Haemodialysis: Dialysate and Water Sample Collection for Microbiological Testing and Replacement of Filters on Portable Reverse Osmosis (RO) Units.</th>
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</thead>
<tbody>
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<td>Procedure</td>
</tr>
<tr>
<td>Document Number</td>
<td>NNSW-LHD-PRO-0197-17</td>
</tr>
<tr>
<td>Superseded Document</td>
<td>N/A</td>
</tr>
<tr>
<td>Sites/Services where compliance with this procedure is mandatory.</td>
<td>NNSW LHD Renal Dialysis Services</td>
</tr>
</tbody>
</table>

**Related Ministry of Health PDs, LHD Documents or Australian Standards:**
- NSW Health Risk Matrix
- NC-NNSW-PRO-7549-15 Aseptic technique
- NC-NNSW-POL-7685-16 LHD Infection Prevention and Control Program
- PD2017_013 Infection Prevention and Control Policy

**Links to National Safety & Quality Health Service Standards (NSQHS):**
- NSQHS Standard 1: Clinical Governance
- NSQHS Standard 3: Preventing and Controlling Health Care Associated infections.

**Risk Management**
- Water treatment is one of the most important aspects of ensuring safe and effective delivery of haemodialysis.
- Failure to ensure adequate water quality may pose serious risk of injury to haemodialysis patient.

**Current Risk Rating**
- M – Moderate / Possible

**Targeted Risk Rating**
- O – Moderate / Rare

**Date Created**
- February 2017

**Date of Publication**
- 20 March 2019

**Next Review Date**
- 20 March 2024

**Aboriginal Health Advisory Committee Registration Number**
- CG/18/06
### Author
Karen Moser A/Renal NE  
Mathew Reilly A/Renal NE

### Clinical Authority
Renal Services NNSW LHD

### Management Authority
NNSW LHD Health Care Quality Committee

### Executive Sponsor
Executive Director Nursing and Midwifery

### Key Words
Water for Dialysis  
Renal Haemodialysis

### Summary
Failure to provide adequate water quality may have dire consequences for patient safety. The water to be used for the preparation of haemodialysis fluids requires treatment to achieve the appropriate quality. Water treatment is provided by a pre-water treatment system.

### Date Approved for Electronic Distribution by NNSW LHD A/Chief Executive
20 March 2019

### Signature NNSW LHD A/Chief Executive
Lynne Weir