



Clinical Practice Standards and Procedures for Dialysis Water Quality: 2b: Endotoxin Testing of Dialysis Water

Section: HD

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1.0 PRACTICE STANDARD

1.1. Purpose

The Biomedical Technologist, Renal Dialysis Technician, or Renal Nurse 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 endotoxin testing, and to perform the necessary actions should test results for endotoxin levels exceed the acceptable limits.

1.2. Standards (*based on CSA-ISO*)

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

	Dialysis Water
Endotoxin Concentration	< 0.25 EU/mL
Action Level	0.125 EU/mL

The laboratory assaying technique used for testing endotoxin levels must be as follows:

	Dialysis Water
Assaying Time	Within 4 hours of collection or 24 hours if immediately refrigerated
Assaying Technique	<i>Limulus amoebocyte lysate (LAL) test</i>

The quality of the dialysis water must be verified to meet these standards at the time of installation of the water treatment system. Dialysis water must be cultured weekly for new dialysis ROs for a minimum of one month, or until a pattern has been established (i.e. two consecutive tests have met the standards). Dialysis water must also be cultured weekly if the acceptable limits are exceeded. For established ROs (including portable ROs), monitoring and testing the microbiology of dialysis water must be performed **at least monthly** (or as recommended by the manufacturer).

2.0 DEFINITIONS AND ABBREVIATIONS

Action level Concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels.

<i>Biofilm</i>	Coating on surfaces that consists of microcolonies of bacteria embedded in a protective extracellular matrix. The matrix, a slimy material secreted by the cells, protects the bacteria from antibiotics and chemical disinfectants.
<i>Dialysate (standard)</i>	Aqueous fluid containing electrolytes and usually buffer and glucose, which is intended to exchange solutes with blood during hemodialysis; also known as <i>dialysis fluid</i> , <i>dialyzing fluid</i> , or <i>dialysis solution</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 hemodialysis applications, including the preparation of dialysis fluid, reprocessing of dialysate, preparation of concentrates and preparation of substitution fluid for online convective therapies.
<i>Disinfection</i>	Destruction of pathogenic and other kinds of microorganisms by thermal or chemical means.
<i>Endotoxin</i>	Major component of the outer cell wall of gram-negative bacteria. (See also <i>pyrogen</i> .)
<i>Endotoxin Units (EU)</i>	Units assayed by the LAL test when testing for endotoxins.
<i>Hemodialysis</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.
<i>HPC</i>	Heterotrophic Plate Count.
<i>LAL</i>	<i>Limulus</i> amoebocyte lysate.
<i>LAL test</i>	Assay used to detect pyrogens and measure endotoxin levels.
<i>Microbial</i>	Referring to microscopic organisms, such as bacteria, fungi, and algae.
<i>Microbial contamination</i>	Contamination with any form of microorganism (e.g., bacteria, yeast, fungi, and algae) or with the by-products of living or dead organisms such as endotoxins, exotoxins and cyanobacterial toxins (derived from blue-green algae).
<i>Pyrogen</i>	A substance that can cause fever (elevation of body temperature above 37.8 °C). Symptoms of a pyrogenic reaction may include chills, rigours, nausea, vomiting, and hypotension. (See also <i>endotoxin</i> .)
<i>RO</i>	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

- LAL Sample Kit (*to be determined*)
- Alcohol swabs
- Gloves
- Endotoxin Testing of Dialysis Water Log Sheet

4.0 PROCEDURE

4.1	Dialysis water sample collection. <i>Note:</i> Samples should always be collected <u>before</u> cleaning/disinfection.
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	4.1.1	Collect the sample 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.
	4.1.2	The sample taps should be opened and the water should be allowed to run for at least 60 seconds before a sample is collected in a LAL sampling unit.
	4.1.3	Sample taps should not be disinfected. If insisted, a sterile gauze with alcohol should be used, and the sample should not be collected until all the alcohol has evaporated so as to leave no disinfectant residual in the sample. Bleach or other disinfectant solutions should not be used.
	4.1.4	Collect the appropriate amount (<i>to be determined</i>) of water, or the volume specified by the LAL Sample Kit, in the sampling unit.
	4.1.5	Record the sample location(s), date, time, and initials of the designated tester on the Endotoxin Testing of Dialysis Water Log Sheet.
4.2		Perform the required LAL testing (<i>to be determined</i>).
4.3		Upon getting the results, record the results and the date the results are obtained on the Endotoxin Testing of Dialysis Water Log Sheet.
4.4		Review the results.
	4.4.1	If the endotoxin concentration does not exceed the action level of 0.125 EU/mL, resume routine endotoxin testing of dialysis water the following month. Otherwise, take corrective measures (go to step 4.5).
4.5		Perform corrective action (refer to <i>Process Flowchart</i> below).
	4.5.1	If this is the 1 st sample, retest within immediately (repeat steps 4.1 to 4.4.1).
	4.5.2	If this is the 2 nd sample, contact Biomed, if not already notified, to perform the next steps.
	4.5.2.1	If the endotoxin concentration exceeds 0.25 EU/mL, arrange an <i>emergency</i> disinfection (within 24 hours) of the RO using peracetic acid (i.e., <i>Minnicare</i>) and notify the Nephrologist. Complete a PSLS report. Otherwise, arrange disinfection of the RO using peracetic acid within a week.
	4.5.2.2	Notify the Area Renal Manager, Biomed Risk & Quality, and the Biomed Lead Tech.
	4.5.2.3	Retest the system or portable RO after disinfection with peracetic acid (repeat steps 4.1 to 4.4.1).
	4.5.3	If this is the 3 rd (or more) sample, it is likely that biofilm is present in the water treatment system and must be removed.
	4.5.3.1	Contact the water treatment system vendor for guidance.
	4.5.3.2	Retest the system or portable RO (repeat steps 4.1 to 4.4.1).
	4.5.4	Record the corrective measure taken on the Endotoxin Testing of Dialysis Water Log Sheet.

5.0 DOCUMENTATION CONSIDERATIONS

All endotoxin test results for dialysis water must be recorded on the Endotoxin Testing of Dialysis Water Log Sheet. These results must be reviewed by the Area Renal Manager and Infection Control, and reviewed and signed off by the Nephrologist **every month**.

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 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.
- If bacterial contamination is suspected, but water cultures are negative, it may be necessary to check for the presence of biofilm.
- Erratic colony counts may indicate the presence of biofilm since sloughing of biofilm may occur with release of bacteria into the water.
- Refer to the *Microbial Testing of Dialysis Water* clinical standard for microbiological testing for bacteria.
- Refer to the *Endotoxin Testing of Dialysate* clinical standard for endotoxin testing of dialysate.

7.0 REFERENCES

- CAN/CSA-ISO 11663-11 - Quality of dialysis fluid for hemodialysis and related therapies (Adopted ISO 11663:2009, First edition, 2009-04-15), *Canadian Standards Association*, 2011.
- CAN/CSA-ISO 13959-11 – Water for hemodialysis 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 hemodialysis 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.

8.0 DEVELOPED BY

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FHA Renal Biomedical Technologists and Renal Managers
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11.0 APPROVED BY

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12.0 PROCESS FLOWCHART

