



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

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 dialysate 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)

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

	Standard Dialysate	Ultrapure Dialysate
Endotoxin Concentration	< 0.5 EU/mL	< 0.03 EU/mL
Action Level	0.25 EU/mL	-

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

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

Dialysate must be cultured weekly for new systems for a minimum of one month or until a pattern has been established (i.e., two consecutive tests have met the standards). Dialysate must also be cultured weekly if the acceptable limits are exceeded. For established systems, monitoring and testing the microbiology of dialysate must be performed **at least monthly**. Monthly monitoring will include selecting machines so that samples are collected from **at least two machines each month** and from enough machines so that **each machine is tested at least once per year**.

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.
<i>Ultrapure dialysate</i>	Highly purified dialysis fluid that can be used in place of conventional dialysis fluid or as feed solution for possible further processing to create fluid intended for infusion directly into the blood.

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

- 20 mL syringes (see *Special Considerations* below if performing the *Microbial Testing of Dialysate* procedure as well)
- LAL Sample Kit (*to be determined*)
- Alcohol swabs
- Gloves
- Endotoxin Testing of Dialysate Log Sheet

4.0 PROCEDURE

4.1	Dialysate sample collection.	
	4.1.1	Select the dialysis machines to be tested.
	4.1.1.1	Record the machine IDs, date, time, and initials of the designated tester on the Endotoxin Testing of Dialysate Log Sheet.
	4.1.2	Draw the dialysate sample from the inlet to the dialyzer from each machine being tested.
	4.1.2.1	Get a syringe, two alcohol swabs, and a LAL Sample Kit.
	4.1.2.2	Label the sampling unit with the machine ID, date, and time.
	4.1.2.3	Put on a pair of gloves.
	4.1.2.4	Open the alcohol swab and use it to clean the sample port at the inlet to the dialyzer. Make sure the alcohol swab is fully swabbed over the injection site. Be sure to use a new alcohol swab for each machine.
	4.1.2.5	Discard the alcohol swab after use and give the alcohol time to evaporate.
	4.1.2.6	Using a new alcohol swab, fold the swab into a triangular shape and use the pointed end to clean the inside of the sample port.
	4.1.2.7	Discard the swab and let the alcohol evaporate.
	4.1.2.8	Using a syringe, aspirate dialysate out of and into the port before filling the syringe. Discard the filled syringe.
	4.1.2.9	Use another new and sterile syringe to collect a fresh sample of dialysate.
	4.1.2.10	Inject the dialysate sample into the sampling unit. Be careful to not touch any inside part of the sampling unit. If the inside of the sampling unit comes into contact with anything, including the syringe or gloves, discard it and use a new one.
	4.1.2.11	Collect the appropriate amount (<i>to be determined</i>) of fluid, or the volume specified by the LAL Sample Kit, in the sampling unit.
	4.1.2.12	Firmly seal the sampling unit. Discard the syringe.
	4.1.2.13	Repeat steps 4.1.2.1 to 4.1.2.12 for each machine being tested.
	4.1.2.14	Alternatively, if the hemodialysis machine permits, the dialysate sample can be drawn from the outlet of the dialyzer . This should be done aseptically by collecting a “free/clean” catch sample after allowing dialysis fluid to run for 30 to 60 seconds.
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 Dialysate Log Sheet.	
4.4	Review the results.	
	4.4.1	If the endotoxin level is less than 0.5 EU/mL (0.03 EU/mL for ultrapure dialysate), resume routine endotoxin testing of dialysate the following month (i.e., on other machines). 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 the offending machine immediately (repeat steps 4.1.2 to 4.4.1.) <i>Note:</i> If the endotoxin level is 0.25 EU/mL or greater (0.03 EU/mL for ultrapure dialysate), the offending machine must also be reselected for endotoxin testing the following month.

	4.5.2	If this is the 2 nd sample:	
		4.5.2.1	Remove the offending machine from service and immediately disinfect the machine using peracetic acid (i.e., <i>Minncare</i>).
		4.5.2.2	Notify the Area Renal Manager, the Biomed Lead Tech, Biomed Risk & Quality, and the Nephrologist.
		4.5.2.3	If the microbial count exceeds 0.25 EU/mL (0.03 EU/mL for ultrapure dialysate), retest the offending machine after disinfection with peracetic acid and <i>do not</i> return the machine to service until <u>after</u> the lab results of this retest are returned. Complete a PSLS report. Otherwise, retest the offending machine after disinfection with peracetic acid and, if necessary, the machine <i>may</i> be returned to service <u>before</u> the lab results of this retest are returned.
	4.5.3	If this is the 3 rd (or more) sample, it is likely that biofilm is present in the machine and must be removed.	
		4.5.3.1	Contact the manufacturer for guidance.
		4.5.3.2	Retest the offending machine (repeat steps 4.1.2 to 4.4.1).
	4.5.4	Record the corrective measure taken on the Endotoxin Testing of Dialysate Log Sheet.	

5.0 DOCUMENTATION CONSIDERATIONS

All endotoxin test results for dialysate must be recorded on the Endotoxin Testing of Dialysate 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

- If performing the *Microbial Testing of Dialysate* procedure at the same time, a larger syringe may be used to collect dialysate for both samples at the same time.
- While taking samples, it is important that no contact is made with the inside of the sampling unit, the end of the syringe, or the clean injection site.
- The procedure should be done when the system is operating under stable conditions representing normal operation.
- The procedure should be done when there is concentrate in the dialysis machine.
- The procedure should not be done within a 2-hour period following a heat clean procedure as the sample may be too warm.
- Refer to the *Microbial Testing of Dialysate* clinical standard for microbiological testing for bacteria.
- Refer to the *Endotoxin Testing of Dialysis Water* clinical standard for endotoxin testing of dialysis water.

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.

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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

