



# Clinical Practice Standards and Procedures for Dialysis Water Quality: 1a: Microbial 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 microbial testing, and to perform the necessary actions should test results for microbial counts exceed the acceptable limits.

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

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

	Standard Dialysate	Ultrapure Dialysate
<b>Total Viable Microbial Count</b>	< 100 CFU/mL	< 0.1 CFU/mL
<b>Action Level</b>	50 CFU/mL	-

The laboratory assaying technique used for testing microbial growth must be as follows:

	Standard Dialysate		Ultrapure Dialysate
<b>Acceptable Test Methods</b>	Pour plate, spread plate, membrane filter techniques		
<b>Preferred Test Method</b>	Spread plate	Pour plate	Membrane filtration
<b>Preferred Sample Volume</b>	0.1-0.3 mL	0.1-1.0 mL	10-1,000 mL
<b>Assaying Time</b>	Within 4 hours of collection or 24 hours if immediately refrigerated		
<b>Culture Media</b>	TGEA or R2A		
<b>Incubation Temperature</b>	17 to 23 °C		
<b>Incubation Time</b>	168 hours (7 days)		

The calibrated loop technique is not an acceptable assay procedure, and blood agar and chocolate agar must not be used as culture media. For ultrapure dialysate, follow the requirements and instructions of the manufacturer of the dialysis machine.

Dialysate must be cultured weekly for new systems for a minimum of one month or until a pattern has

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

<i>Action level</i>	Concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels.
<i>Colony forming unit (CFU)</i>	Measure of bacterial or fungal cell numbers that theoretically arise from a single cell or group of cells when grown on solid media; a cell or group of cells capable of replicating to form a distinct, visible colony on a culture plate.
<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>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>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>R2A</i>	Reasoners 2A.
<i>RO</i>	Reverse osmosis.
<i>TGEA</i>	Tryptone glucose extract agar.
<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 *Endotoxin Testing of Dialysate* procedure as well)
- HPC Total Count Samplers
- Alcohol swabs
- Gloves
- Microbial 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 Microbial Testing of Dialysate Log Sheet.
	4.1.2	Draw the dialysate sample from the <b>inlet to the dialyzer</b> from each machine being tested.
	4.1.2.1	Get a syringe, two alcohol swabs, and a HPC Total Count Sampler.
	4.1.2.2	Label the sampler 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. <b>Be sure to use a new alcohol swab for each machine.</b>
	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 HPC Total Count Sampler. <b>Be careful to not touch any inside part of the sampler.</b> If the inside of the sampler comes into contact with anything, including the syringe or gloves, discard it and use a new one.
	4.1.2.11	Collect 17 mL of fluid, or the volume specified by the laboratory performing the testing, in the HPC Total Count Sampler.
	4.1.2.12	Firmly seal the sampler. 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 <b>outlet of the dialyzer</b> . 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	Send the samples to the Microbiology Laboratory for testing.	
	4.2.1	Fill out a lab requisition for each sample.
	4.2.2	Attach the lab requisitions to the respective samples.
	4.2.3	Submit the samples to the Microbiology Lab.
4.3	Upon receiving the results from the Microbiology Lab, record the results and the date the results are received on the Microbial Testing of Dialysate Log Sheet.	
4.4	Review the lab results.	
	4.4.1	If the microbial count does not exceed the action level of 50 CFU/mL (0.1 CFU/mL for ultrapure dialysate), resume routine microbial 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 <sup>st</sup> sample, retest the offending machine immediately (repeat steps 4.1.2 to 4.4.1). <i>Note:</i> If the microbial count is 100 CFU/mL or greater (0.1 CFU/mL or greater for ultrapure dialysate), the offending machine must also be reselected for microbial testing the following month.
4.5.2	If this is the 2 <sup>nd</sup> (or more) sample:
4.5.2.1	Remove the offending machine from service and immediately disinfect the machine using peracetic acid (i.e., <i>Minnicare</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 100 CFU/mL (0.1 CFU/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.
4.5.2.4	Perform troubleshooting: <ul style="list-style-type: none"> <li>• Collect and test samples from other parts of the dialysis system.</li> <li>• Evaluate/correct sample collection technique.</li> <li>• Evaluate/correct compliance with disinfection procedure (refer to <i>Cleaning and Disinfection of Dialysis Water Equipment</i> clinical standard).</li> <li>• Evaluate microbial data for previous 3 months to look for trends.</li> </ul>
4.5.3	Record the corrective measure taken on the Microbial Testing of Dialysate Log Sheet.

## 5.0 DOCUMENTATION CONSIDERATIONS

All microbial test results for dialysate must be recorded on the Microbial 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 *Endotoxin 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 sampler, 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 *Endotoxin Testing of Dialysate* clinical standard for microbiological testing for endotoxins.
- Refer to the *Microbial Testing of Dialysis Water* clinical standard for microbial 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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12.0 PROCESS FLOWCHART

