



# Clinical Practice Standards and Procedures for Dialysis Water Quality: 1b: Microbial Testing of Dialysis Water

Section: HD

Origin Date: November 2011

Reviewed Date: November 2011

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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 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*)

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

|                                     | Dialysis Water |
|-------------------------------------|----------------|
| <b>Total Viable Microbial Count</b> | < 100 CFU/mL   |
| <b>Action Level</b>                 | 50 CFU/mL      |

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

|                                      | Dialysis Water  |
|--------------------------------------|---|
| <b>Preferred Test Method</b>         | Membrane filtration   |
| <b>Other Acceptable Test Methods</b> | Pour plate, spread plate  |
| <b>Assaying Time</b>                 | Within 4 hours of collection<br>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.

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

|                                  |  |
|----------------------------------|--|
| <i>Action level</i>              | 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>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, dialyzing fluid, or 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.   |

*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

- HPC Total Count Samplers
- Alcohol swabs
- Gloves
- Microbial Testing of Dialysis Water Log Sheet

## 4.0 PROCEDURE

|     |  |  |
|-----|--|--|
| 4.1 | Dialysis water sample collection.<br><i>Note:</i> Samples should always be collected <u>before</u> cleaning/disinfection.      |  |
|     | 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.<br>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 HPC Total Count Sampler.   |
|     | 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 17 mL of water, or the volume specified by the laboratory performing the test, in the HPC Total Count Sampler.   |
|     | 4.1.5  | Record the sample location(s), date, time, and initials of the designated tester on the Microbial Testing of Dialysis Water Log Sheet.   |
| 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 on the Microbial Testing of Dialysis Water 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, resume routine microbial testing of dialysis water the following month.<br>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 immediately (repeat steps 4.1 to 4.4.1).   |
|     | 4.5.2  | If this is the 2 <sup>nd</sup> sample, contact Biomed, if not already notified, to perform the next steps.   |
|     | 4.5.2.1  | If the microbial count exceeds 100 CFU/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.<br>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  | Initiate troubleshooting protocol: <ul style="list-style-type: none"> <li>• Collect and test samples from other parts of the distribution loop (applicable to RO systems only).</li> <li>• Evaluate/correct sample collection technique.</li> <li>• Evaluate/correct compliance with disinfection procedures (refer to <i>Cleaning and Disinfection of Dialysis Water Equipment</i> clinical standard).</li> <li>• Evaluate/correct water system components.</li> <li>• Evaluate microbiological data for the previous 3 months to look for trends.</li> </ul> |
|     | 4.5.2.4  | 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 <sup>rd</sup> (or more) sample, determine whether the equipment should be removed from patient use. |
|  |       | 4.5.3.1 Retest the system or portable RO (repeat steps 4.1 to 4.4.1).  |
|  | 4.5.4 | Record the corrective measure taken on the Microbial Testing of Dialysis Water Log Sheet.                            |

## 5.0 DOCUMENTATION CONSIDERATIONS

All microbial test results for dialysis water must be recorded on the Microbial 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 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 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 *Endotoxin Testing of Dialysis Water* clinical standard for microbiological testing for endotoxins.
- Refer to the *Microbial Testing of Dialysate* clinical standard for microbial 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.

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NHA Renal Biomedical Technologists and Renal Program Technicians and Managers  
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**

BCPRA Medical Advisory Council – November 2011

12.0 PROCESS FLOWCHART

