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NEPHROLOGY PROGRAM
DEPARTMENT POLICIES AND PROCEDURES

Biomed Neph - Section 03 - Water Quality Management - Neph Tech 3-01
Microbiology Monitoring Procedure
No.: 01065 (TOH Standardized Policy Number)

ISSUED BY:
Nephrology Technical Practice Committee

DATE OF APPROVAL:
N/A

APPROVED BY:
Program Clinical Director / Division Head

LAST REVIEW/REVISION DATE:
2017/03

CATEGORY:
Water Quality Management

IMPLEMENTATION DATE:
2007/04

PURPOSE:

- To sample and obtain bacterial results of treated water and dialysate solution on a routine basis

FREQUENCY:

- Monthly on all in-centre water treatment systems (portable systems included)
- Monthly on all home Hemodialysis machines and water treatment systems (including non-R.O. systems)
- Quarterly on all in-center Hemodialysis machines (quantity evenly distributed over a monthly basis)
- Microbiology testing procedure shall be completed in conjunction with Endotoxins testing

DEFINITION(S): N/A

ALERTS: N/A

SUPPLIES REQUIRED:

- Millipore samplers (inventory # 320600)
- Alcohol swabs (inventory # 230660)
- Microbiology Request Form (# Lab 16 01/2006 Cat:412735)
- Mask and gloves

PROCEDURE:

To obtain bacteria results from In-Center water treatment systems including portable systems:

1. Put on mask and gloves and gather the required supplies
2. Sample systems using aseptic technique
3. Sample systems in locations as indicated on the Equipment Maintenance Log sheets according to the frequency indicated
4. Where available, clean sample port with alcohol swab and rinse for two (2) minutes
5. Remove paddle from Millipore sampler and collect water sample to the upper fill line
6. Insert the paddle into the Millipore sampler
7. Lay Millipore sampler face down for 30 seconds
8. Remove paddle and dispose of fluid from Millipore sampler
9. Insert the paddle back into the Millipore sampler
10. Label sampler and place face down in a cold environment (2 to 4 degrees C) until the sampler can be shipped to the Microbiology Lab for analysis
11. Fill out appropriate Microbiology Request Form for each sample
12. Enter information in NephroCare database and Equipment Maintenance Logsheet
13. Fill the Bacteriology/Endotoxins Testing Result Sheet and send to the Technical Manager or his delegate
14. Results exceeding 50 CFU per ml will be reported by the laboratory to the Technical Manager or his delegate for appropriate action (maximum allowed is 100 CFU per ml)

To obtain bacteria results from Home Hemodialysis water treatment systems (including non-R.O. system):

1. Put on mask and gloves and gather the required supplies
2. Sample systems using aseptic technique
3. Locate the water input line at the rear of the Hemodialysis machine. Disconnect the quick connect from water supply
4. Clean and disinfect the end of quick connect and connector to be used with alcohol swab and rinse for two (2) minutes
5. Remove paddle from Millipore sampler and collect water sample to the upper fill line
6. Insert the paddle into the Millipore sampler
7. Lay Millipore sampler face down for 30 seconds
8. Remove paddle and dispose of fluid from Millipore sampler
9. Insert the paddle back into the Millipore sampler

10. Label sampler and place face down in a cold environment (2 to 4 degrees C) until the sampler can be shipped to the Microbiology Lab for analysis
11. Fill out appropriate Microbiology Request Form for each sample

12. Enter information in NephroCare database and Equipment Maintenance Logsheet
13. Fill the Bacteriology/Endotoxins Testing Result Sheet and send to the Technical Manager or his delegate
14. Re-install the water input line on the Hemodialysis machine and secure the hose clamp
15. Results exceeding 50 CFU per ml will be reported by the laboratory to the Technical Manager or his delegate for appropriate action (maximum allowed is 100 CFU per ml)

To obtain bacteria results from Hemodialysis machines (including home hemodialysis machines):

1. Put on mask and gloves and gather the required supplies
2. Sample Hemodialysis machines on a quarterly basis (quantity evenly distributed over a monthly basis) using aseptic technique
3. Dialysate samples are obtained from the dialysate sample port or equipment manufacturer approved method
4. Remove paddle from Millipore sampler and collect water sample to the upper fill line
5. Insert the paddle into the Millipore sampler
6. Lay Millipore sampler face down for 30 seconds
7. Remove paddle and dispose of fluid from Millipore sampler
8. Insert the paddle back into the Millipore sampler
9. Label sampler and place face down in a cold environment (2 to 4 degrees C) until the sampler can be shipped to the Microbiology Lab for analysis
10. Fill out appropriate Microbiology Request Form for each sample
11. Enter information in NephroCare database and Equipment Maintenance Logsheet
12. Fill the Bacteriology/Endotoxins Testing Result Sheet and send to the Technical Manager or his delegate
13. Results exceeding 50 CFU per ml will be reported by the laboratory to the Technical Manager or his delegate for appropriate action (maximum allowed is 100 CFU per ml)

Action steps to be followed for in-centre equipment results:

1. Contact Technical Manager or his delegate

Action steps to be followed for home Hemodialysis equipment results:

RO PRODUCT WATER	HEMODIALYSIS MACHINE WATER	ACTION REQUIRED
Less than 50 CFU/ml	Less than 50 CFU/ml	No action required
Between 50 and 100 CFU/ml	Less than 50 CFU/ml	1-) Patient can dialyze following disinfection of RO system 2-) Microbiology resample to be done ASAP (within 48 hours)
Over 100 CFU/ml	Less than 50 CFU/ml	1-) Patient can dialyze following disinfection of RO system 2-) Microbiology resample to be done ASAP (within 48 hours) 3-) If retest is still positive, patient can no longer dialyze at home until situation gets resolved
X	Between 50 and 100 CFU/ml	1-) Patient can dialyze following disinfection of Hemodialysis machine 2-) Microbiology resample to be done ASAP (within 48 hours) 3-) If retest is still positive, patient can no longer dialyze at home until situation gets resolved
X	Over 100 CFU/ml	1-) Patient can not dialyze at home until steps 2, 3 and 4 below are completed 2-) Hemodialysis machine must be disinfected 3-) Microbiology resample to be done same day as disinfection gets done 4-) No growth must be confirmed through Microbiology Lab (72 hours incubation) before patient can resume home dialysis

NOTES:

1. Take one sample (only one) from RO water treatment system (i.e. do not double-up on samples)
2. Always sample the Hemodialysis machine at the same time as sampling the RO system
3. Do not alter sampling dates on Equipment Maintenance Log Sheets when re-sampling following positive results

RELATED POLICIES / LEGISLATION:

1. Nephrology Policies and Procedures - Biomed Neph - Section 01 - Equipment Maintenance - Neph Tech 1-07 (#01060) NephroCare Work Orders

2. Nephrology Policies and Procedures - Biomed Neph - Section 03 - Water Quality Management - Neph Tech 3-02 (#01066) Endotoxins Testing Procedure

REFERENCES:

1. CSA-ISO 13959-15 *Water for haemodilaysis and related therapies*
2. CSA-ISO 26722-16 *Water treatment equipment for haemodialysis applications and related therapies*
3. CSA-ISO 13958-15 *Concentrates for haemodialysis and related therapies*
4. CSA-ISO 11663-15 *Quality of dialysis fluid for haemodialysis and related therapies*
5. CSA Standard Z364.5-10 (R2015) *Safe Installation and Operation of Hemodialysis and Peritoneal Dialysis in a Home Setting*
6. Bacteriology/Endotoxins Testing Result Sheet (Rev. June 18, 2015)

COMMENTS / SIGNIFICANT REVISIONS: N/A