



Rancho Los Amigos National Rehabilitation Center  
DEPARTMENT OF NURSING  
ADMINISTRATIVE  
POLICY AND PROCEDURE

**SUBJECT:** HEMODIALYSIS: WATER, DIALYSATE &  
ENDOTOXIN BACTERIOLOGY TESTING,  
NURSING GUIDELINES, AND STORAGE OF  
MACHINES & SUPPLIES

Policy: A190.12

Effective Date: July 3, 2023  
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**PURPOSE:** To identify and reduce the risk of infections in dialysis patients

**POLICY STATEMENTS:**

**Action Limits:**

- Reverse Osmosis (RO) water and Dialysate Microbial Count equal to or greater than 50 CFU/ml
- RO water and Dialysate Endotoxin level greater than 1.0 EU/ml

**Critical Values:**

- Reverse Osmosis (RO) Water and Dialysate Microbial Count greater than 200 CFU/ml
- RO water and Dialysate Endotoxin level greater than 2.0 EU/ml
- Chemical monitoring above AAMI maximum levels of chemical contaminants

**Dialysis Corrective Action Plan:** Written plan developed, implemented, reviewed by Infection Control (IC) and kept on file.

**PROCEDURE:**

**I. Testing Requirements**

- a. Monthly bacterial and endotoxin testing shall be collected from Reverse Osmosis (RO) and machine (dialysate) water on all dialysis machines and portable RO systems.
- b. Water analysis for chemical contaminants to be performed:
  - i. At least semi-annually
  - ii. When new RO system installed
  - iii. When membranes are replaced.
- c. Testing results are to be sent to the Dialysis Service – Medical Safety Officer, Nurse Manager (NM), Clinical Nursing Director (CND), and Infection Control (IC), and reviewed immediately.

**II. Action Limits**

- a. Action limit values exceeding the parameters are to be called to the dialysis nurse manager or nursing director immediately. Nurse manager will inform the Medical Safety officer and Infection Control of out-of-range results.
- b. Machine with out-of-range testing result will be identified, tagged, and taken out of service.
- c. Machine will be disinfected and re-cultured as soon as possible
- d. Copy of the results of re-culture must be sent to the Dialysis Nurse Manager
- e. A corrective action plan will be developed, implemented, reviewed by IC and kept on file

**III. Critical Value**

- a. Critical values are to be reported to nurse manager immediately and IC notified if during normal working hours
- b. Nurse manager to ensure that water and/or dialysate critical values are within allowable limits
- c. Machine must be identified, tagged, and taken out of service immediately with corrective action taken

- d. Water, dialysate, and endotoxin testing to be performed prior to any interventions (pre-disinfection)
- e. A copy of the re-culture test results will be sent to the dialysis nurse manager
- f. A corrective action plan will be developed, implemented and reviewed by IC
- g. The corrective action plan will be submitted, signed off by the Dialysis Nurse Manager and Nephrologist and kept on file
- h. The IC Department must approve the reuse of the dialysis machine with critical values before it can be reused for patients
- i. Cultures should be repeated when bacterial counts exceed the allowable levels. If culture growth exceeds permissible standards, the water system and dialysis machines should be cultured weekly until acceptable results are obtained. Additional samples should be collected when there is clinical indication of pyrogenic reaction or septicemia

#### **IV. Corrective Action Measures for Action Limit and Critical Value**

- a. Communicate and provide copy of out-of-range result to Medical Safety officer, CND and Infection Prevention
- b. Identify and tag machine "Out of Service - Do not use" and take machine out of service
- c. Clean and disinfect machine and portable RO system per policy and procedure
- d. Review water culture collection procedure with Dialysis Team
- e. Re-culture machine ASAP and NOT used until result is within the normal limits
- f. Provide copy of re-culture result to Medical Safety officer, CND and Infection Prevention.

#### **V. Collection of Bacteriological Samples**

- a. RO water, endotoxins, and dialysate
  - i. Run water for at least 60 seconds
  - ii. Do not disinfect sample tap
  - iii. Collect a "clean catch" specimen and process according to laboratory policy
  - iv. Specimens to be processed within 24 hours of collection
  - v. Water and dialysate shall be packed and refrigerated to ensure an environment of less than 10°C, if analysis cannot occur within 4 hours of collection
  - vi. Chemical monitoring of treatment water must be performed annually
- b. Dialysate
  - i. Only sample ports shall be utilized
  - ii. Disinfect port with alcohol and allow to air dry
  - iii. Use a 30 ml sterile syringe to aspirate dialysate out of the port, then discard the syringe
  - iv. Take a fresh sample using a new sterile syringe each time
  - v. Transfer sample into a sterile endotoxin free container and send at 36-46 degrees to the lab
- c. Culture samples (RO water and dialysates) should always be collected before sanitation/disinfection of water treatment systems and dialysis machines. Fluid sampling for microbiological testing should be performed no sooner than 24 hours after disinfection to avoid negative results
- d. For new machines and portable RO system culture weekly until pattern has been established

#### **VI. Dialysis Nursing Guidelines**

- a. Chloramine testing
  - i. To be performed prior to each dialysis
  - ii. Chloramine to be tested after first carbon tank
  - iii. Maximum level; <0.1 mg/l
- b. When shunt or central venous catheter is used for vascular access, a new sterile antimicrobial dressing is to be applied after each dialysis treatment.
- c. External surfaces top, front, wheels and side surfaces, dialysate hoses, connectors, and outside surfaces of dialysate containers) are to be cleaned and disinfected after each patient use, using only hospital approved disinfectants (1:100 bleach solution). Disinfectants used must be able to kill Blood borne pathogens. Manufacturer's instructions and contact time must be adhered at all times.
- d. Single use of disposable acid concentrate/bicarbonate container to be disposed of upon completion of treatment
- e. A Biohazardous trash can must be made available upon the start of treatment. Bloodlines and other disposable supplies meeting the biohazardous definition must be disposed of properly in the Biohazardous bins
- f. Appropriate Protective Personal Equipment (PPE) must be used during treatment and for cleaning of equipment
- g. Only supplies that are needed for treatment are to be brought into the room. No personal equipment or supplies (i.e. backpacks, jackets, computers, lunch bags, purse, cell phones, iPod, etc.)
- h. Unused supplies must be discarded or dedicated to patient. No supplies returned to supply room
- i. Disposable equipment should be used whenever possible. If reusable equipment must be used, manufacturer's cleaning instructions must be adhered to after each use
- j. Whenever possible, the patient will be given priority for a private room with a private bathroom and handwashing sink. If a private room is not possible, roommate must be given instructions and arrangements made for use of another restroom during treatment
- k. For non-private rooms used during dialysis, housekeeping must be notified following treatment in order to disinfect the sink and bathroom
- l. Hospital Policy on Hand Hygiene must be strictly followed

### **VII. Storage of Machines**

- a. The Dialysis Machine Storage Room must be kept clean. It is the responsibility of the Dialysis Team to maintain the room in a clean and orderly fashion. Must be clear of any dust, dirt, debris, or clutter. For housekeeping issues or to have the trash emptied collaborate with EVS service
- b. Dialysis supplies will be inspected for expiration date. Any supplies that have expired will be removed immediately. Supplies that have been opened or no longer sterile will be disposed
- c. Dialysis machines will be always cleaned and disinfected prior to use, following manufacturer's instructions for cleaning machines.

### **VIII. Monitoring and Documentation**

- a. The Dialysis Nurse Manager or NCD will have direct oversight in assuring that compliance with this policy is being followed
- b. The Dialysis Nurse Manager will be responsible for assuring that all testing requirements for water, dialysate and endotoxins are completed and submitted monthly and are within acceptable limits
- c. If there is a critical or action level water, dialysate or endotoxin test result, a corrective action plan will be initiated by the Dialysis Nurse Manager or and submitted per directions in section III. Critical Value (see above).

- d. The dialysis nursing supervisor will keep an up-to-date binder which will include all policies and procedures and all testing requirements.
- e. The binders shall be made available to any regulatory agency upon request
- f. If any testing results are out of range the Dialysis nurse will notify the appropriate staff responsible for the machine and request an immediate corrective action plan
- g. The Dialysis Nurse Manager will notify the Department of IC of any out-of-range testing results.
- h. The Dialysis RN/Tech will inspect the Dialysis Storage Room(s) monthly to perform supply inventory and check for expired supplies and equipment including cleanliness of the area

References:

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Association for the Advancement of the Medical Instrument. *Sterilization Central: Water Quality in medical device Processing: The power of prevention*. Retrieved 5/26/23.

Association for the Advancement of the Medical Instrument: ISO 23500 Series: *Ensuring Quality of Fluids for Hemodialysis and Related Therapies*

Association for the Advancement of the Medical Instrument: *The Microbial World and Fluids in Dialysis*

CDC. *Recommendations for Preventing Transmission of Infections among Chronic Hemodialysis Patients*.

Fresenius Medical Care. Operator's Manual 2008T Machine Operator's Manual P/N 490122 Rev Z

Olive View Nephrology Policy and Procedures. Policy Number 11766

Rancho Los Amigos Infection Prevention and Control Policy number IC100

Rancho Los Amigos Policy C109- *Transfusion of Blood Products and Colloid Solution*

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