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PREVENTING SPECIFIC "HIGH RISK" PROBLEMS TYPICALLY ASSOCIATED WITH DIALYZER REPROCESSING

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Note: Information and recommendations in this guideline are based on the author's personal experience working with personnel from more than 100 dialysis facilities, working with dialyzer manufacturers, and personal research to solve the problems listed herein (from 1983 through 2002).

Released February - 1992.
Revised June -1992, Sept. - 1993, Sept. - 1996, Sept. - 1998, Dec. - 2002

INTRODUCTION

Dialyzer reprocessing can be a safe and effective practice if performed properly with appropriate quality control measures in place. However, dialyzer reprocessing will not be safe, just as a dialysis treatment will not be safe, if performed improperly or if quality control is not taken seriously.

Many dialysis centers experience problems with some aspect of providing a dialysis treatment including dialyzer reprocessing. How significant reprocessing problems are and how frequent they occur, will depend largely on the dialysis center's quality control of the entire dialysis and dialyzer reuse process.

Quality control measures are not likely to be as effective when implemented before identifying potential high-risk problems and the mechanisms that can cause these problems. These "high risk" problems are defined as problems that may result in injury or death to dialysis patients.

Certain "high risk" problems reoccur periodically in different dialysis centers across the country. Some of these problems have been unfairly associated with dialyzer reprocessing procedures. Investigations have shown the problems had originated elsewhere in the dialysis treatment procedures. However, problems have originated within a center's dialyzer reprocessing program.

Specific "high risk" problems and their suggested solutions are shown on the following pages. This information is not meant to be an exhaustive listing, nor is it a replacement for medical decision-making.

It is meant to be an informative overview targeted to high risk problems that have been reported by various dialysis centers throughout the United States. By providing this information, the mechanisms that most often cause problems associated with dialyzer reprocessing, can be addressed effectively in quality control procedures.

Important Note:

> Warnings, cautions and instructions for use for chemical cleaners and germicides referenced, are not included in this guideline. Personnel using any of the chemicals referenced, or any other chemical, are expected to comply with all appropriate warnings, cautions and instructions for use. Should any of the following problems occur in your center, the Safe Medical Devices Act of 1990 requires you report the incident as soon as possible but no later than 10 working days after you become aware of the incident. Reports of death must be made to the Food & Drug Administration (FDA) and to the manufacturer if known. Reports of serious injuries or illness must be made to the manufacturer or to FDA if the manufacturer is not known. User facilities must submit a semiannual report to FDA summarizing the reports.

PYROGENIC AND BACTEREMIC REACTIONS

PROBLEM: Excessive bacteria growth in purified water or bicarbonate solutions not detected by laboratory or by paddle type samplers.

SOLUTION: Select a laboratory that understands requirements for testing various dialysis samples. See the article in the Appendix entitled: "How to Choose a Laboratory" by J. Maltais, Ph.D. (reprinted with permission of the author). Validate paddle sampler results against results from a more standard test such as the pour plate technique, especially when testing bicarbonate solution samples. Samples should be taken just before system disinfection to see "worst case" conditions.

RATIONALE: Many laboratories used to working with blood samples, have used inappropriate culture media for water and bicarbonate solution samples. In addition, the amount of water sampled is often insufficient to provide accurate, repeatable results with test sensitivities to less than 1 Colony Forming Unit (<1 CFU). Results from paddle samplers have deviated significantly from results obtained using more conventional methods.

PROBLEM: Excessive bacterial growth and/or endotoxin units in purified water used for reprocessing dialyzers and/or making bicarbonate concentrate solutions.

SOLUTION: Increase frequency of water system disinfection procedure. Perform procedure on a maintenance basis (typically every 2 weeks in centers using high flux dialyzers). Disinfect water system at least monthly. Do not rely on culture results alone as an indication of need to disinfect your system. A biofilm could be building in your system or the culture results may be in error as stated above. Action must be taken promptly, to reduce colony count and endotoxin levels, if the water system colony counts reach 50 CFU/mL, or the endotoxin concentration reaches 1EU/mL (ANSI/AAMI RD62:2001). Verify concentration of disinfectant and dwell period are appropriate to kill the bacteria in your system. Disinfect R.O. membranes, holding tank, recirculation loop and EACH DIALYSIS MACHINE WATER INLET LINE. Eliminate long dead legs or branches from your recirculation loop. If manual-reprocessing system is in a dead leg, re-plumb it so that each station is a short extension from the loop. Do not allow dialyzers to sit for more than a few minutes while filled with water. Do not depend on refrigeration to retard growth of all bacterial species, e.g. Yersinia and Listeria grow in cold temperatures.

RATIONALE: Bacteria are opportunistic microorganisms and without an appropriate system design and maintenance schedule, they will ultimately proliferate in your R.O system. Centers using high flux dialyzers have a greater potential risk as the more permeable membranes may allow bacteria and/or endotoxin in the dialysate to elicit patient reactions

PROBLEM: Excessive bacterial growth in bicarbonate concentrate.

SOLUTION: Disinfect bicarbonate concentrate mixing system daily, containers at least weekly. Mixing system tanks should have conical taper bottoms to facilitate drainage (this is also true of water system holding tanks). Allow disinfectant to flow through tank faucet soon after placing disinfectant in tank. Disinfectant should be allowed to dwell in tank until next batch of bicarbonate concentrate is to be made. Make sure disinfectant concentration is adequate to kill bacteria in the dwell time established. Rinse the tank with PURIFIED WATER, which is nearly bacteria free (meets ANSI/AAMI RD62 quality requirement – less than 50 CFU/mL, less than 1 EU/mL), until the germicide concentration in the rinse water is below the maximum allowable residual level. Drain all effluent water before making bicarb batch. Should it not be practical to hold disinfectant in mixing tank overnight, make sure rinse water drains thoroughly and does not pool in the tank. Keep faucet open so that water does not stagnate inside faucet. Bicarbonate concentrate machine containers should be filled 20 - 25% with disinfectant, capped and inverted to make sure disinfectant touches all inner surfaces Remove caps pour out disinfectant. Rinse containers with PURIFIED WATER, which is nearly bacteria free, until germicide concentration in the rinse water is below the maximum allowable residual level. Pour out the water. Invert the open containers for residual drainage and allow to air dry in this position until needed again. If large batches of bicarbonate concentrate are stored for up to seven days, consider using an ultraviolet, recirculation storage system.

RATIONALE: Frequent disinfection of bicarbonate concentrate mixing and storage systems is essential to control colony counts present in the final dialysate. The number of bacteria present in the final dialysate takes on added significance when using high flux dialyzers. Bacteria adapted to bicarbonate solutions grow quickly. Bacteria can grow in bicarbonate concentrate to unacceptable levels in one 24-hour period. Rinse water can be the source for bacteria. Standing pools of water, after tank drainage, should be eliminated or bacteria will grow in these pools or in water trapped in the faucet.

PROBLEM: Introduction of bacteria or endotoxin after removing ring-caps to clean dialyzer header area.

SOLUTION: Clean header area by flushing header surface with germicide stream from a vented, washbottle. Germicide used must be the same as that used within dialyzer during storage. Do not use water sprays or water rinsing to clean the header area. Bacteria may grow in areas of the header that cannot be reached by germicide once header cap is reattached.

RATIONALE: Any bacteria trapped in the header area may be released to the blood under conditions present within the dialyzer during treatment.

PROBLEM: Inadequate bacterial kill within the dialyzer.

SOLUTION: Final aqueous formaldehyde concentration delivered to the dialyzer should be 4 percent and allowed to dwell in the dialyzer for 24 hours at a temperature of at least 20 degrees C. Lower concentrations of formaldehyde can be used at higher temperatures if validated as effective. Peracetic acid (PAA) based solutions for dialyzer reprocessing (Micro-X, Renalin, or Peracidin) should be an unexpired 3 - 3.5 percent solution allowed to dwell in the dialyzer for 11 hours at room temperature. PAA solutions should not be heated. Mix germicide solutions thoroughly. Do not rely on the flow force of the dilution water to mix germicides. Ovens used for heat disinfection (or heating dialyzers filled with formaldehyde) must be checked periodically to verify temperature controls are working properly. Consider quantitative testing for the presence of formaldehyde/glutaraldehydes instead of dyes. Do not put dye in PAA solutions. If you are using a manual system, make sure volume of blood compartment and dialysate compartment are both exchanged at least 3 times with germicide before capping for storage. Consider using ultrafiltration of final germicide when manually reprocessing high flux dialyzers (see procedure at end of rationale section). Your dialyzer filling procedure must guarantee that blood and dialysate side final germicide concentrations are at least 90 percent of the prescribed concentration.

RATIONALE: Four percent formaldehyde for twenty-four hours at 20 degrees C or greater is a Centers for Disease Control recommendation. Less concentrated solutions or a shorter dwell time at 20 degrees C may result in failure to kill certain resistant bacteria such as nontuberculus mycobacteria. 3 - 3.5 percent PAA based dialyzer-reprocessing germicide (Micro-X, Renalin, or Peracidin) for eleven hours, at no greater than 25 degrees C, are the germicide manufacturer's specifications for use with automated reprocessing systems. Temperature controllers on ovens may malfunction causing the dialyzer to be over or under-heated. Dyed solutions in dialyzers cannot be used reliably to determine that adequate germicide concentrations exist within the dialyzer. Dye in PAA based germicides may increase the rate of peracetic acid decay, compromising the germicidal characteristics of the chemical solution. Displacing the volume of each dialyzer compartment three times or more, with germicide, minimizes the potential for residual water retained in the dialyzer to dilute the germicide. Large high flux dialyzers may retain significant amounts of rinse water in their intracellular space (as much as 40 percent of total dialyzer volume). Rinse water retained in this space may not be adequately displaced during germicide fill procedures. After filling the blood compartment with germicide, (3X) consider capping the blood compartment outlet port with a disinfected cap and allow germicide flow to continue into the blood compartment and through the membrane until it is evident coming out of the dialysate compartment. Cap remaining blood port. Fill dialysate compartment (3X) and cap.

ALLERGIC REACTIONS

PROBLEM: Pre-cleaning or cleaning dialyzers with overly concentrated peroxide, sodium hypochlorite or peracetic acid based dialyzer reprocessing germicide solutions.

SOLUTION: Eliminate use of chemicals in pre-cleaning or cleaning procedure except as indicated here: Match chemical, concentration and rinse out time with same chemical, concentration and rinse out time used by CLEANING process in your automated system and recommended by your automated system manufacturer. Use low concentrations of cleaning chemicals in manually reprocessed dialyzers and do not use more than one type of cleaning chemical in the process. Typical concentrations that have been used for cleaning are a maximum of 0.5% peroxide, 0.25% sodium hypochlorite and 2.0% peracetic acid based solution (Micro-X, Renalin, or Peracidin). Manual system operators should validate that rinse time is always adequate to remove the cleaning agent. Rinse to less than trace levels (without rebound) if an unlike germicide will be introduced in the same dialyzer. Test rinse solution with an appropriate residuals test and record the results to document this step, for each dialyzer, or for a random sample of dialyzers.

RATIONALE: High concentrations of chemicals can be absorbed by the dialyzer-header potting compound and later leached into the dialyzer blood and/or dialysate compartment. Increasing the concentration of chemical cleaners above a validated, safe level may cause many problems including: allergic reactions, poor reuse, dialyzer potting compound deterioration/case cracking, etc.

PROBLEM: Inadequate dilution and/or mixing of germicide resulting in highly concentrated or layered solution.

SOLUTION: Emphasize importance of dilution and thorough mixing of germicide to personnel responsible for the task. Prepare a sign-off sheet and require initials of the individual preparing each batch of germicide. Add appropriate amount of purified water, cap and agitate small containers of germicide solution for at least 30 seconds. Add appropriate amount of water, and thoroughly stir germicide solution, in large containers, for at least 30 seconds. DO NOT RELY ON FLOW FORCE OF PURIFIED WATER TO MIX GERMICIDE SOLUTION. Test each dialyzer before pre-dialysis rinse with an appropriate presence test (not dye). Monitor dialyzer germicide rinse time. Longer than normal rinse times for a cluster of dialyzers may mean the batch of germicide used for these dialyzers was not prepared properly.

RATIONALE: Inadequate dilution and/or mixing of germicide solutions will result in delivery of high or high/low concentrations (layered solution) to dialyzers. High concentrations of germicide can be absorbed by the dialyzer header potting compound and

RATIONALE: (cont'd) later leached into the blood and/or dialysate compartments. This is similar to the problem that occurs with excessive concentrations of peroxide, sodium hypochlorite, or peracetic acid in solutions used for cleaning dialyzers. If the germicide is not mixed properly, potency testing of each dialyzer before rinsing will show a large variation in results on dialyzers reprocessed from that germicide batch.

PROBLEM: Germicide rebound post dialyzer rinse.

SOLUTION: Make sure germicide has been diluted and mixed properly as stated elsewhere in this overview. Set blood pump speed at a minimum of 300 ml/min and UFR at 2 liters (or kilograms) per hour during germicide rinse out period e.g. 500 ml in 15 min. = 2 L/hr. After rinse and residual test procedure are complete, set minimum UF rate or TMP to make sure a small amount of ultrafiltrate continues to flow to the dialysate. Continue this procedure until the patient is ready for treatment. If ultrafiltrate flow toward the dialysate must be discontinued, perform another test for residual germicide. Restart dialyzer rinsing and rinse until residual germicide is at an acceptable level, before starting the patient treatment.

RATIONALE: Rebound is less likely to occur when dialyzers have been filled with properly diluted and mixed germicide solutions. Dialyzer header potting compounds can have sponge-like characteristics. Excess concentrations of germicide may saturate the potting compound making it unlikely the dialyzer will rinse normally i.e. it is likely there will be significant rebound after typical rinse time. Maintaining a slight ultrafiltrate flow to the dialysate reduces the risk of undetected residual germicide accumulating in the blood compartment

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PROBLEM: Reaction to type of heparin in use.

SOLUTION: Exercise appropriate medical decision for patient involved. Consider monitoring heparin lot numbers, date codes, type, manufacturer and regimen used for each patient. This action will help detect changes that may result in later problems

BLOOD LEAKS

PROBLEM: Dialyzers are being mechanically stressed during the reprocessing procedure.

SOLUTION: Reduce purified water flow rate through dialysate compartment to one liter per minute or less at no greater than 30 psig regulated pressure. Use a 1-liter per minute flow restrictor in dialysate side flush line for each dialyzer station in manual systems. In automated systems, check with equipment manufacturer to determine if flow through dialysate side can ever exceed 1 liter/min for your serial number reprocessing machine. Storage area for dialyzers should be maintained at even temperatures i.e. room temperature - 20-25 C. Do not store dialyzers near hot water heaters. Pressure test each dialyzer and be aware of test limitations e.g. negative pressure applied on dialysate side with blood side open to atmosphere will not detect blood leaks from loose header rings. Inspect header rings for tightness before placing dialyzer in storage.

RATIONALE: High flow flushing on the dialysate side of the dialyzer presents more potential for rupturing fibers than high flow flushing on the blood side. This increased potential for fiber rupture occurs as a result of water velocity shearing energy present as the flow is forced to make a right angle turn. Fibers at the dialysate inlet, which absorb this energy, are the fibers most likely to rupture or become stressed. Fibers that have been forced away from the bundle during high speed blood side flushing are at additional risk of stress or rupture. Some dialyzer models are at greater risk, for fiber rupture, than others (depends on dialyzer design characteristics such as case restriction to flow, how well fibers are bundled, membrane thickness, etc.). Thermal cycling during storage may stress dialyzers and may contribute to dialysate channeling.

PROBLEM: Excessive mechanical stress generated by aggressive chemical reactions in blood compartment during pre-cleaning or cleaning process

SOLUTION: Eliminate use of chemicals in pre-cleaning or cleaning procedure except as indicated here: Match chemical, concentration and rinse out time with same chemical, concentration and rinse out time used by CLEANING process in your automated system and recommended by your automated system manufacturer. Use low concentrations of cleaning chemicals in manually reprocessed dialyzers and do not use more than one type of cleaning chemical in the process. Typical concentrations that have been used for cleaning are a maximum of 0.5% peroxide, 0.25% sodium hypochlorite and 2.0% peracetic acid based solution (Micro-X, Renalin, or Peracidin). Manual system operators should validate that rinse time is always adequate to remove the cleaning agent. Rinse cleaner to less than trace levels (without rebound) if a different chemical will be introduced in the same dialyzer (as a germicide) before storage. Automated or manual systems exposed to excessive concentrations of a cleaner or germicide,

SOLUTION: (cont'd) should be rinsed thoroughly with purified water through the chemical connection line(s) and sanitized before use.

RATIONALE: Peroxide, sodium hypochlorite and peracetic acid based solutions, are oxidizing chemicals that give off gas while denaturing blood loads in the dialyzer. Excessive concentrations of these chemicals may react aggressively against the blood load, causing mechanical expansion and contraction forces that may stress or rupture fibers. Automated or manual systems exposed to excessive concentrations of cleaners or germicides may leach additional amounts of these chemicals into the dialyzer fluid streams even after discontinuing use of improperly mixed solutions. This action is similar to chemical rebound that occurs in dialyzer header potting compounds.

PROBLEM: Fiber(s) damaged by needle puncture while withdrawing a germicide sample for concentration or presence test.

SOLUTION: Remove one dialysate cap and squeeze the remaining cap on the dialyzer to push out a small amount of germicide for concentration or presence test. Do not use a syringe/needle to puncture the dialysate cap and draw a sample.

PROBLEM: Blood leaks occurring on dialyzers that have previously passed automated or manual pressure tests during reprocessing.

SOLUTION: Qualified personnel should check and validate pressure-testing function in automated machines according to the manufacturers procedure. Manual system pressure test function should be checked and validated against source procedure e.g. AAMI/ANSI Standard for First Use Hemodialyzers. Follow all other suggestions listed in this section as the dialyzer may have been stressed during the reprocessing procedure but not enough to fail the pressure test.

RATIONALE: Equipment should be tested and maintained as directed, by manufacturer or internal procedures, to ensure pressure test function works properly. Dialyzers that leak blood after having worked properly, for even a short time into the treatment, will have passed the prior reprocessing pressure test as the failure occurred during the treatment. It is highly likely that pre-stressed dialyzers will leak blood more often than non-stressed dialyzers. Blood leaks with pre-stressed dialyzers may occur as a result of the following combined dialysis elements that are not all present during the reprocessing procedure: ultrafiltration (not reverse UF), pH shift, significant temperature rise over a short time period, and TMP fluctuations.

PARTICULATE IN DIALYZERS

PROBLEM: Particulate in dialyzer compartments.

SOLUTION: Validate reprocessing procedure does not effect dialyzer materials, for each use, up to a designated maximum use e.g. potting compound deterioration, dialyzer case stress cracking. Set maximum use number accordingly. Note: A volume and/or pressure test may not detect the presence of particulate in a dialyzer. Check concentration of cleaning agents or germicides. High concentrations of chemical solutions may be the source of this problem (as well as other problems listed elsewhere in this overview).

RATIONALE: Reprocessing procedures will ultimately compromise dialyzer mechanical integrity. How soon this happens depends on several variables, including concentration of chemicals used during the reprocessing procedure. Evaluation and validation of reprocessing procedures effect on dialyzer mechanical integrity, for each reuse, can minimize or eliminate problems due to particulates from deterioration and dialysate channeling.

INADEQUATE DIALYSIS ASSOCIATED WITH REUSE

PROBLEM: Patient receives insufficient dialysis dose due to under-performing reprocessed dialyzer(s)

SOLUTION: Make certain overall reprocessing procedure is effective in restoring each dialyzer TCV to as near 100% as is possible, for each reuse. Monitor pre-clean/clean procedures for efficacy. Discard dialyzer(s) if KUF changes significantly. Model heparin delivery for each patient to minimize potential for loss of dialyzer surface area, from clotted fibers, over multiple uses. Set a maximum use number for each dialyzer type that correlates with proper performance for each use.

RATIONALE: Clotted dialyzer fibers due to inefficient cleaning procedures, or improper heparin delivery, will cause a loss of dialyzer surface area and a corresponding decrease in clearance. In addition, the clearance loss to the patient can be cumulative if the treatment time is not extended to compensate for the loss. Setting a performance validated maximum use number minimizes potential for problems from:

1) Undetected Change to Dialyzer Materials
   - potting compound, case, header & o-rings, fibers

2) Dialysate Channeling in Dialyzer
   - non-uniform dialysate distribution around fibers
   - asymmetrical fiber bundle
   - non-correlating TCV vs. clearance
   - inadequate dialysis due to low clearances

HOW TO CHOOSE A LABORATORY

TO PROPERLY CULTURE WATER AND CONCENTRATE/DIALYSATE SAMPLES
FOR BACTERIAL CONTAMINATION

TO ENSURE COMPLIANCE WITH ANSI/AAMI STANDARDS
FOR HEMODIALYSIS SYSTEMS AND REUSE OF HEMODIALYZERS

In choosing a laboratory to analyze your water, concentrate, dialysate machine water samples or any other "environmental" samples you take to monitor the levels of bacteria in various parts of your dialysis operation, there are several things to consider.

1. Laboratories whose primary function is to process "clinical" specimens, i.e. wound, urine, fecal, sputum, blood samples, may not know how to properly analyze water or dialysate samples. Clinical specimens usually contain high numbers of bacteria and require highly nutritious media for growth. Use of the same media for detection of natural contaminants of water or dialysate will result in poor or no recovery. Make sure that the laboratory agrees to follow the recommended culture techniques listed in #9 below.

2. A calibrated loop technique for culturing water or dialysate/ concentrates is not acceptable. It is not accurate enough. The volume of sample being evaluated by the calibrated loop technique, while adequate when the sample has high concentrations of organisms, is too small for the level of contamination normally expected especially in water samples. The calibrated loop normally samples .01 ml. Since the AAMI Standard for Quality Water allows no more than 200 CFU/ml, a .01 ml sample would only contain 2 CFU. The detection of 2 CFU would not be considered reliable and therefore your water could be over AAMI specifications or within AAMI specifications, but you couldn't be sure based on this test result.

3. Blood Agar or Chocolate Agar plates are not acceptable culturing media. They are too rich an environment for cultivation of bacteria from water or dialysate/concentrate samples.

4. Clinical laboratories normally incubate samples at 37 degrees centigrade for 48 hours. You will need to have them incubate your samples at 35 degrees centigrade or at room temperature, for 72 hours. This is particularly important for culturing bicarbonate dialysate or concentrate.

5. Bicarbonate concentrate or dialysate needs to be cultured using Tryptic Soy Agar or Tryptic Soy Broth. The organisms which proliferate in bicarbonate solutions often require salts particularly sodium chloride. Media used to culture bacteria from water such as Standard Plate Count Agar do not contain sodium chloride and if it is used to culture the bicarbonate samples, detection of such bacteria will be inhibited.

6. A laboratory should be chosen which is located as close as possible to the dialysis center. The "Standard Method for the Examination of Water and Wastewater", 16th edition, 1985 recommends that "The recommended maximum elapsed time between collection and

examination of samples is 8 hours (6 hours transit time , maximum processing time 2 hours)". Refrigeration of samples can often lead to killing off of some organisms particularly some pseudomonads, and the continued growth of others. Therefore, refrigeration of samples is not recommended. Emphasize this to the laboratory you are considering retaining for the processing of your samples.

7. If you or your laboratory use the Millipore Samplers for bacterial analysis of your samples, make sure that the laboratory compares the results they get on your samples with more standard testing methods such as pour plate, spread plate, or membrane filtration techniques. In some cases differences of as much as 3 to 4 logs (1000 to 10000 CFU) have been observed between the recoveries on the Millipore samplers and conventional techniques. However, they may be perfectly fine for your samples. Make sure the laboratory checks. Do not let them tell you that they have validated the samplers compared to more conventional methods at a previous time with someone else's samples. The bacteria in those samples were probably different than those found in your samples and the recoveries may be very different.

8. If you are using the Millipore Samplers, be sure and use the Red ones for your water samples and the White ones for Bicarbonate Dialysate and Bicarbonate Concentrate. For Bicarbonate concentrate samples, you may have to dilute the sample 1:10 in order to get proper wetting of the sampler membrane. If the membrane turns completely dark gray with the concentrate, you are probably all right. If the wetting is spotty or incomplete, dilute the sample 1:10 before using the Millipore Sampler. Make sure you incubate any samplers used for bicarbonate samples for 72 hours. There is one organism in particular which grows slowly and will not be noticeable in 48 hours, but can overgrow the sampler in 72 hours.

9. If you use more conventional methods for culturing your water and bicarbonate samples (pour plate, spread plate, membrane filter technique) make sure that the laboratory uses the proper medium Standard Plate Count Agar for Water Samples and Tryptic Soy Agar for Bicarbonate Samples. If the membrane filter technique is used, it is important to incubate for 72 hours, as the organisms often take longer to grow using this technique.

10. If the laboratory you are considering will not meet your requirements, look for another laboratory. You will save yourself much grief, aggravation and work in the long run.

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