Panel of Pioneers: Perspective and Predictions

Speakers:
V. Taaffe, J. Maltais, G. Rovegno, R. Ward
Increasing Importance of Biomed Techs

In a Changing Dialysis World
Input from the Experts

Thank you to all who contributed comments:

- Danny Concepcion – St. Joe’s., Orange, CA.
- Mark Rolston – FMCNA
- Chuck Weddle – IDF
- Bruce Fife - USRC
- John Dahlin – FMCNA
- Doyle Siglin – FMCNA
- Nick Grimley - RPC
- Mike Lorenson – RPC
- Dan Forde - RPC
- Multiple people (12) – RenalWEB
Perspective on the Past

☑ One biomed for 1 or 2 clinics (common)
  - Limited travel

☑ Responsibilities of biomed technicians
  - Repair/maintain non-complex equipment
  - Inventory control (informal) for 1 or 2 clinics
  - Procedure management in relation to regulatory requirements of the time (for 1 or 2 clinics)
  - Manage dialyzer reuse program (where applicable)
  - In-service training & misc. support for staff

☑ Training of biomed technicians
  - Education budget allowed outside training on a routine basis (e.g. equipment, professional development, etc.)
Sluggish Reimbursement Rate
Consolidation

- RCG Acquires NNA
- DaVita Acquires Gambro
- FMC Acquires RCG
- RAI Acquires NRA
Regulation
Equipment Evolution

Drake-Willock 4002
Travenol RSP
Fresenius 2008K
B. Braun Dialog
Gambro Phoenix
Perspective on the Present

- One biomed for multiple clinics (common)
  - Considerable travel

- Responsibilities of biomed technicians
  - Repair/maintain complex equipment (software driven)
  - Inventory control (formal) for multiple clinics
  - Procedure management in relation to greatly increased regulatory requirements
  - Manage dialyzer reuse programs (where applicable)
  - Provide multiple clinics w/ training & misc. support

- Training of biomed technicians
  - Education budget emphasizes receipt of training from within the dialysis provider organization
Do You Agree?

- Sluggish reimbursement rate
- Consolidation
- Increased regulation
- Equipment evolution

... have all contributed to a critical need for Biomed Techs to take on a greater number of tasks and increased responsibility.
Predictions for the Future

• Increased visibility

• Greater recognition

• Higher compensation rate for biomeds that have expanded responsibilities and certification.
Make it a Bright Future

With:

- Confidence & positive attitude
- Certification
- Continuing education

... the critical need for Biomed Techs can be converted to an opportunity for advancement and career growth, for those that can adapt.
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Infection Control & Equipment Disinfection
Rhetoric, Reality & Future

Jo-Ann B. Maltais, Ph.D.
NANT 27th Annual National Symposium
Las Vegas, NV
March 3, 2010
Infection Control is the Responsibility of Everyone Involved in the Dialysis Treatment Process
CHRONIC HEMODIALYSIS PATIENTS AT HIGH RISK FOR INFECTION

- Long-term vascular access; need for routine access to bloodstream for therapy delivery
- Immunosuppressed state
- Concurrent treatment along with other patients
- Frequent hospitalization and surgery
- Exposure to infectious agents—bacteria & viruses
  - Person to person transmission
  - Contaminated devices, equipment, supplies
  - Environmental surfaces
  - Hands of personnel
  - Nosocomial infections in hospital & clinic environments
- Extended courses of antibiotic treatment
INFECTION CONTROL--RHETORIC

- Too many patients
- Too many regulations
- Too much paperwork
- Too little time
- Too few resources
- Need to focus on patient treatment
- No time for training
- We do the best we can!
INFECTION CONTROL--REALITY

- Number of dialysis patients continues to rise
  - 309,269 patients were treated for ESRD in U.S. in 2004
  - Twice the number treated in 1994
- Infection is the 2nd most common cause of death
  - Accounts for 14% of mortality
- The number of new and resistant bacteria and viruses continue to rise (MRSA, VRE, H1N1)
- Clinics cited for Infection Control Non-Compliance
  - 58 clinics under TAG 110
Clinic resources continue to decline; training budgets reduced

- Compliance with vaccination, monitoring and hygiene requirements is inconsistent
- Immunosuppressed patients require higher vaccine doses, multiple dosing, frequent monitoring and limited exposure to infectious agents
- More time, More resources, More expense
More Training Will Be Needed To:

- Increase awareness of infectious agent sources & how transmitted
- Focus on steps each person can take in their position to reduce the risk of transmission of infectious agents to patients

- BioMed Techs
  - Water treatment systems—maintenance and control
  - Concentrate preparation and delivery—risks & responses
  - Hemodialysis system maintenance & disinfection
  - Monitoring and trending—respond to early warnings
  - Validation of control systems and frequency of disinfection
  - Periodic audits for regulatory compliance
Better products and processes to make compliance with regulation & infection control practices more efficient will be forthcoming

- Electronic patient records
- More stringent bacterial & endotoxin limits
- Improved system designs for bacterial, endotoxin & biofilm control and removal (e.g. ozone disinfection, heat disinfection)
- Validation of systems & processes by manufacturers
- Verification and control by BioMed Techs

Work smarter, not harder!
BIOMED TECHS MAKE A DIFFERENCE

- Water Treatment System
- Concentrates & Dialysate
- Dialysis Machines
- Dialyzer Reuse
DISINFECTION WATER TREATMENT SYSTEM
WHAT MATTERS

- Design of System
- Disinfectant Used
- Concentration
- Dwell Time
- Residuals
- Frequency

Ryder, M. Medical Biofilm Research
TargetBSI.com Webinar 7/28/09
Disinfectants and Biofilm

Hypochlorite Penetrates Biofilm Slowly

![Graph showing the penetration of hypochlorite into biofilm](image1)

- Chlorine Concentration (mg/L) vs. Depth (microns)
- Time points: 5460 s, 1511 s, 47 s

H$_2$O$_2$ fails to Penetrate Biofilm

![Graph showing the failure of H$_2$O$_2$ to penetrate biofilm](image2)

- Time (seconds) vs. Hydrogen Peroxide Concentration (mM)
- Catalase reaction: H$_2$O$_2$ $\xrightarrow{\text{catalase}}$ H$_2$O + 1/2O$_2$
- Base of biofilm

References:
2. Stewart et al., 2001
Appl Microbiol 91:525-532.

3. Stewart et al., 2000
BIOFILM IN WATER SYSTEMS AND MEDICAL DEVICES

Ryder, M. Medical Biofilm Research
TargetBSI.com Webinar 7/28/09

Donlan, RM. Biofilm Laboratory. CDC
Once monthly disinfection adequate for all water treatment systems
No detectable bacteria and/or acceptable levels of endotoxin = No Biofilm
Turbulent flow in the loop prevents any biofilm formation
Filters only need to be changed at manufacturer recommended intervals
Water Treatment System—Reality

- Water Quality is clinically relevant and a patient safety issue
- Consolidation has increased BioMed Tech responsibilities
  - Increased number of clinics to service
  - Mix of system designs to maintain
  - Older water treatment systems not being replaced due to cost constraints
    - Technology can be the same as 25 years ago
    - Larger diameter piping, long distance loops, storage tanks and system shut down times increase risk of biofilm formation
    - Additional effort is needed to keep systems operational and in compliance with regulatory requirements
- Less training time & budgets available
Regulations and documentation requirements are increasing
- Old Medicare Regs = 4 TAGS related to water and dialysate
- 2008 CFC = 64 TAGS related to water

Top deficiencies related to water—

<table>
<thead>
<tr>
<th>#</th>
<th>TAG #</th>
<th>TAG Description</th>
<th># Cited</th>
<th>% of Surveys</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>V196</td>
<td>Carbon adsorption—Monitoring, testing, frequency</td>
<td>96</td>
<td>10.1%</td>
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<tr>
<td>39</td>
<td>V187</td>
<td>Environment—Schematic diagrams/labels</td>
<td>55</td>
<td>5.8%</td>
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<tr>
<td>49</td>
<td>V260</td>
<td>Personnel—Training program/periodic audits</td>
<td>45</td>
<td>4.7%</td>
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<tr>
<td>53</td>
<td></td>
<td>Softeners—Testing hardness/log</td>
<td>41</td>
<td>4.3%</td>
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</tbody>
</table>

Source: Glenda M Payne, ESRD Technical Advisor, Centers for Medicare & Medicaid Services, Dallas & Atlanta Regions
Surveys completed: 948 of 5477 providers
WATER TREATMENT SYSTEM--FUTURE
GREATER EFFICIENCY, LOWER OPERATING COSTS

- Distribution loop velocity readouts
- RO membranes with higher rejection rates, lower operating pressures
- Electrodeionization
- Old systems replaced with new designs with lower operating costs
- New piping materials—less bacterial adhesion, tolerance to more aggressive disinfection (e.g. ozone or heat)
- Comprehensive automated daily sanitization/disinfection
WATER TREATMENT SYSTEM--FUTURE
GREATER EFFICIENCY, LOWER OPERATING COSTS

- More stringent bacterial and endotoxin level requirements
- In-line monitoring systems to detect biofilm and bacterial/endotoxin levels
- Better methods of removing biofilm
- Ultrapure dialysate requiring ultrapure water
- Validated process and process controlled systems
THE GOAL

Standard Dialysis Quality Water ➔ Ultrapure Water

Fig. 1. Tubing segment, showing complete absence of biofilm, from a water treatment system delivering ultrapure water.

Fig. 2. Tubing segment, showing extensive biofilm formation, from a standard water treatment system.
CONCENTRATES & DIALYSATE--RHE TORIC

- It is OK to mix old and new batches of bicarbonate concentrate
- Biofilm doesn’t form in bicarbonate concentrate
- Containers don’t need to be disinfected once emptied of bicarbonate concentrate
- Water quality doesn’t matter for Acid Concentrate
- Dialysate contaminants don’t cross dialyzer membranes
CONCENTRATES & DIALYSATE--REALITY

- Old Medicare Regs = 4 TAGS related to water & dialysate
- 2008 CFC = 28 TAGS related to dialysate
- Bicarbonate concentrate can form biofilm on the inside of containers
  - Disinfect with high level disinfectant/sterilant frequently and dry completely
- Mixing old and new batches of bicarbonate concentrate can result in changes in pH and concentration
- Acid concentrate if prepared with water containing large numbers of bacteria can result in endotoxin contamination
- Dialysate contaminants bacterial debris and endotoxin can cross dialyzer membranes by diffusive backfiltration
# Concentrates & Dialysate Reality—CFC Citations

<table>
<thead>
<tr>
<th>TAG #</th>
<th>TAG Description</th>
<th># Cited</th>
<th>% of Surveys</th>
</tr>
</thead>
<tbody>
<tr>
<td>V250</td>
<td>Dialysate proportioning—monitor pH/conductivity</td>
<td>87</td>
<td>9.2%</td>
</tr>
<tr>
<td>V175</td>
<td>Water &amp; Dialysate Quality</td>
<td>32</td>
<td>3.4%</td>
</tr>
</tbody>
</table>

Source: Glenda M Payne, ESRD Technical Advisor, Centers for Medicare & Medicaid Services, Dallas & Atlanta Regions
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CONCENTRATES & DIALYSATE--FUTURE

- On-line generation of bicarbonate concentrate
- More stringent bacterial and endotoxin limits
- Increased use of ultrafilters to meet more stringent requirements
- Ultrapure dialysate production at point of use or via central delivery systems
The dialyzer prevents transmission of bacteria and endotoxin to patient so water and dialysate levels are irrelevant.

Post disinfection sampling tells me the machine meets AAMI acceptable levels.

As long as my monthly monitoring results are OK on a % of the dialysis machines, all of them are within limits and I don’t need to be concerned or have to trend my data.
DIALYSIS MACHINES--FUTURE

- AAMI Standards likely to move closer to European (ISO) Standards—lower bacterial and endotoxin limits
- Validation and process control required
- On-line convective therapies may increase—Ultrapure dialysate, sterile substitution fluid
- Increased use of in-line ultrafilters for ultrapure dialysate as standard of care
DIALYSIS MACHINES--REALITY

- Both low & high flux dialyzers can allow transfer of bacteria & endotoxin from dialysate to patient by backfiltration.
- Pre-disinfection sampling of a % of the dialysis machines/month gives a snapshot, it doesn’t tell you what is happening in all machines all of the time.
- Post disinfection sampling only tells you whether the disinfection procedure is effective or not.
Employment expected to grow 27% over the next 9 years

Faster growth than the average for all occupations

The aging population puts more people at risk for developing ESRD
  - Growth of this segment of the population is expected to be faster than that of the total population

Dialysis patient population is expected to increase (doubled in the UK over past 10 years)
Patient Safety and Delivery of Quality Therapy is--
YOU CAN MAKE A DIFFERENCE

BIO MED TECHS ROCK!
Panel of Pioneers: Perspective and Predictions

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Perspective and Predictions: EMRs

George Rovegno
MIQS Software
Perspective

- EMRs can improve quality, reduce costs
- EMRs make the necessary information readily available to the caregiver at the point of care
- EMRs manage workflow and prevent things from falling through the cracks
- EMRs are cheap and not much used
Predictions

- Lack of skilled personnel will force IT solutions into healthcare. Substitute IT for people
- Accountability
- Quantification
The roles of EMRs

- **Care implications**
  - IT = Individualize Treatment
  - Managing huge volumes of data at the point of care – Amount of data – Reporting of data
  - Using the data
  - Quality of care–team approach–efficient delivery
  - Integral quality tools

- **Financial implications**
  - Quality rewards & penalties
  - Financial survival
The CfCs require individualized care and the surveyors are enforcing this rule.
- Regular (annual/monthly) assessments drive comprehensive care plans with mandatory follow-up and revision – teams of caregivers
- Assessment & PoC must be data driven – this requires computers and relational databases.
Large amounts of data require EMRs
Quality of Care

- Outcomes & Quality – evidence based medicine requires lab values
  - Whatever happened to CQI?
  - Outcomes vs. Process
  - Ratings and scores – like dialysis compare – public disclosure, more items

- Accountability – tech credentialing
Process (CQI)
Documentation

- Pay for what you document not just what you do
- Time stamps, sign offs, P & Ps
- If you document it correctly you avoid trouble and are paid correctly the first time.

"Our professional staff has determined that the services were medically necessary and properly documented."
Physician MCP: Some Early Results

Billing data on 243 patients treated by HD in a single Dialysis Unit in March 2004*  
(In Feb 2004 <70% of possible was documented)

<table>
<thead>
<tr>
<th></th>
<th>Recorded (#)</th>
<th>Maximum (#)</th>
<th>Percent of possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comprehensive encounter</td>
<td>232</td>
<td>243</td>
<td>95.5%</td>
</tr>
<tr>
<td>Brief encounter</td>
<td>709</td>
<td>729</td>
<td>97.3%</td>
</tr>
<tr>
<td>Billed G0317 (1 Comp &amp; 3 Brief encounters)</td>
<td>231</td>
<td>243</td>
<td>95.1%</td>
</tr>
<tr>
<td>Billed G0318 (1 Comp &amp; 1-2 Brief encounters)</td>
<td>10</td>
<td>243</td>
<td>4.1%</td>
</tr>
</tbody>
</table>

- Used wireless laptop computer on rounds
- Major effort made to utilize the software to record encounters
- Major administrative feedback to ensure physician compliance
MIQS: Giving EPO During HD Run

An EPO Order on the HD Run Screen must be addressed. Nurse documents administration or NON administration and signs off.
MIQS: Checking EPO at HD Sign off

Nurse Signs off at End of HD Treatment

A warning appears if the ordered EPO was not recorded as given-management tool.
ESRD QIP – reporting & quantification
9 Topic areas for 26 measures:
  ◦ Anemia, Dialysis Adequacy (Hemodialysis and Peritoneal Dialysis), Vascular Access, Mineral Metabolism, Influenza Vaccination, Mortality, and Patient Education, Satisfaction, and Quality of Life.
  Will determine payments & penalties
HCIT

- Healthcare is a major anomaly among information-intensive businesses – over $2T revenue business spending under 2% of revenue on IT. Not on EMRs least exploited is the core of the business, clinical operations and clinical data.
- cottage–industry nature, resistance of providers to be measured on their performance
The Future

- More IT use
- Increasing scrutiny
- ESRD is a model for all healthcare
- Quantification of quality
- Global bundling
- Lower payments for more work
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CHLORAMINE REMOVAL:

Is carbon always the answer?

Richard A. Ward
FREQUENT CHLORAMINE BREAKTHROUGH

• Several dialysis units in the same geographical area obtain water from municipalities that draw their water supply from lakes.

• Units use exchangeable carbon tanks with an EBCT ≥ 10 minutes.

• Chloramine breakthrough occurs within a week of exchanging tanks.

• What’s going on and what can be done to control chloramine levels without needing to constantly be changing carbon tanks?
USE OF CHLORAMINE TO DISINFECT WATER SUPPLIES

- Chloramines are formed by adding ammonia to chlorinated water.
  - $\text{HOCl} + \text{NH}_3 \rightarrow \text{NH}_2\text{Cl} + \text{H}_2\text{O}$ (monochloramine)
  - $\text{HOCl} + \text{NH}_2\text{Cl} \rightarrow \text{NHCl}_2 + \text{H}_2\text{O}$ (dichloramine)
  - $\text{HOCl} + \text{NH}_2\text{Cl}_2 \rightarrow \text{NCl}_3 + \text{H}_2\text{O}$ (trichloramine)

- The form of chloramine is pH dependent. At pH > 7, monochloramine is the most prevalent form.

MW = 51.5 Da
THE FORM OF CHLORAMINE DEPENDS ON pH
CHLORAMINE CONTENT OF TAP WATER

Added to water as an alternative disinfectant to chlorine to reduce the formation of carcinogenic trihalomethanes.
REMOVAL OF CHLORAMINE

- Carbon adsorption with granular activated carbon is generally the most effective means of removing chloramines.
- Two beds are connected in series to give a total EBCT of $\geq 10$ minutes.
- Testing for chloramine between the beds is used to prevent disruptions in operation following unanticipated breakthrough.

Image courtesy of FMS
REMOVAL OF CHLORAMINE BY CARBON
CARBON REMOVES CHLORAMINE VIA AN OXIDATION REACTION

- Two reactions take place at the carbon surface:
  - \( \text{C}^* + \text{NH}_2\text{Cl} + \text{H}_2\text{O} \rightarrow \text{NH}_3 + \text{H}^+ + \text{Cl}^- + \text{CO}^* \)
  - \( \text{CO}^* + 2\text{NH}_2\text{Cl} \rightarrow \text{N}_2 + \text{H}_2\text{O} + 2\text{H}^+ + 2\text{Cl}^- + \text{C}^* \)

- The reaction rate for monochloramine oxidation of carbon is much slower than the rate for oxidation by hypochlorous acid/hypochlorite ion.

- Catalytic carbon is carbon that has been modified to have more surface reaction sites.
EFFECT OF pH ON CHLORAMINE REMOVAL

EFFECT OF NATURAL ORGANIC MATERIAL ON CHLORAMINE REMOVAL

WHAT CAN REDUCE THE EFFECTIVENESS OF CHLORAMINE REMOVAL BY CARBON?

- Substances that prevent monochloramine from reaching the reactive sites on the carbon surface.
  - Corrosion inhibitors, such as orthophosphate.
  - Organic material in the water.

- Conditions that slow the rate of reaction.
  - Low temperature.
  - High pH.
WHAT ARE THE OPTIONS WHEN CARBON PROVIDES INADEQUATE CHLORAMINE REMOVAL?

- Remove substances that mask reactive sites.
- Adjust the temperature and pH for optimal carbon performance.
- Use alternative methods of removal.
ALTERNATIVES AND SUPPLEMENTS TO CARBON ADSORPTION

- **ANION EXCHANGE RESINS (ORGANIC SCAVENDER)**
  - Remove organic matter and other substances that may foul carbon.

- **CHEMICAL INJECTION SYSTEMS**
  - pH adjustment for optimal carbon adsorption.
  - Sodium bisulphite reduces chlorine species to chloride.

- **REDOX ALLOY MEDIA (KDF RESIN)**
  - Copper/zinc alloys that reduce chlorine species to chloride.
  - Limited pH range.
  - Not effective with orthophosphate and polyphosphate.

- **ULTRAVIOLET IRRADIATION**
  - Converts chlorine species to chloride (254 nm).
  - Breaks down organic species (185 nm).
**ALTERNATIVES AND SUPPLEMENTS TO CARBON ADSORPTION**

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INJECTION SYSTEMS

- CONTROL THE RATE OF INJECTION
  - Acid injection can be controlled by pH
  - Bisulfite injection can be controlled by oxidation-reduction potential (ORP)

- FOR ACID INJECTION
  - Use a mineral acid
  - Select a target pH consistent with proper operation of other purification processes
# EFFECT OF pH ON FLUORIDE REMOVAL

<table>
<thead>
<tr>
<th>DATE</th>
<th>pH</th>
<th>FEED (mg/L)</th>
<th>POST-HCl (mg/L)</th>
<th>PRODUCT (mg/L)</th>
<th>RO REJECTION (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>JAN 02</td>
<td>10</td>
<td>0.79</td>
<td>0.005</td>
<td>0.011</td>
<td>99</td>
</tr>
<tr>
<td>MAR 02</td>
<td>7</td>
<td>0.79</td>
<td>0.77</td>
<td>0.011</td>
<td>99</td>
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<tr>
<td>APR 02</td>
<td>7</td>
<td>0.76</td>
<td>0.76</td>
<td>0.015</td>
<td>98</td>
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<tr>
<td>JUL 02</td>
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<td>0.81</td>
<td>0.81</td>
<td>0.005</td>
<td>99</td>
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<tr>
<td>OCT 02</td>
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<td>0.86</td>
<td>0.81</td>
<td>0.073</td>
<td>91</td>
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<tr>
<td>JAN 02</td>
<td>6</td>
<td>0.85</td>
<td>0.88</td>
<td>0.884</td>
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**HCl INJECTOR INSTALLED IN PRE-TREATMENT**

<table>
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<tr>
<th>DATE</th>
<th>pH</th>
<th>FEED (mg/L)</th>
<th>POST-HCl (mg/L)</th>
<th>PRODUCT (mg/L)</th>
<th>RO REJECTION (%)</th>
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<tr>
<td>FEB 02</td>
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<td>0.81</td>
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<td>80</td>
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<tr>
<td>FEB 02</td>
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<td>0.85</td>
<td>0.005</td>
<td>96</td>
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<tr>
<td>MAR 02</td>
<td>8</td>
<td>0.86</td>
<td>0.87</td>
<td>&lt; 0.01</td>
<td>99</td>
</tr>
</tbody>
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EFFECT OF pH ON ALUMINUM IN WATER

TESTING FOR TOTAL CHLORINE

- $N$-chloramines (organic chloramines) will test positive in DPD-based assays.
- Other oxidizing agents (e.g., permanganate) will test positive in DPD- and MTK-based assays.
- Manganese oxides interfere with DPD-based assays, but not MTK-based assays.
  - $N$-chloramines and permanganate are rejected by reverse osmosis.
  - If you suspect interference in the DPD assay, measure total chlorine after the RO.
CHLORAMINE REMOVAL

• Levels in municipal water are a moving target.
• Establish communications with your water provider.
• Other changes in municipal water may impact on the ability of carbon to remove chloramine.
• When installing an alternative means for chloramine removal, think how it will impact the rest of the treatment system.
• If there is unexpected breakthrough, think about possible interferences with the chloramine assay.
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