Serim
RESEARCH CORP

GUARDIAN™ Dialysis Test Strips

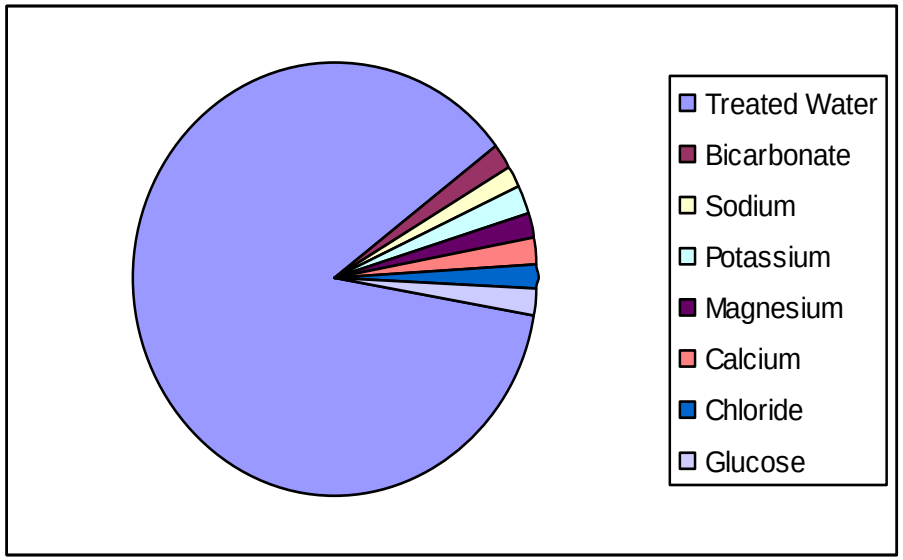
Hemodialysis & Water Quality

- In hemodialysis, blood is removed from the body and filtered through a dialyzer, or artificial kidney.
- Waste products from the blood are drawn into the dialysate by diffusion.

- The filtered blood is returned to the body and the dialysate/waste products go down the drain.

Hemodialysis & Water Quality

Dialysate = treated water + bicarb concentrate + acid concentrate



Since dialysate is mostly water, the quality of the water is extremely important.

Hemodialysis & Water Quality

- Municipal water treatment plants add disinfectants to make water safe for drinking.
- Commonly used water disinfectants:
  - Chlorine
  - Chloramine (free chlorine + ammonia)
    - Even if chloramine is not normally present in feed water, chloramine can form naturally from chlorine combining with ammonia from decomposing vegetation.

Hemodialysis & Water Quality

- Chloramine is safe in drinking water because it is neutralized in the digestive system before it enters the bloodstream.
- But, if chloramine comes in direct contact with blood, oxidation can occur, leading to hemolysis of red blood cells.
- Therefore, the disinfectants used to make water safe to drink must be removed before water is safe to use for dialysis.

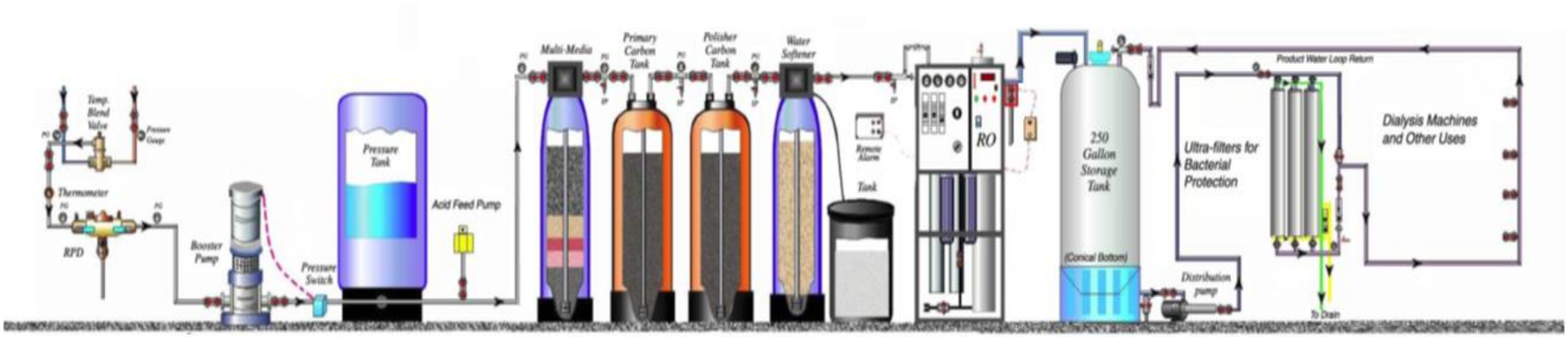
Hemodialysis & Water Quality

- Hemodialysis patients are vulnerable to contaminants in the water used to prepare concentrate and dialysate or in water used for reprocessing dialyzers.
- Municipal water must be treated to remove disinfectants, calcium & magnesium and other contaminants prior to being used in dialysis centers.

Typical Dialysis Water Treatment System

Components

- Backflow Prevention
- Temperature Mixing Valve
- Booster pump
- Chemical Injection Systems (adjusts pH)
- Multimedia filters
- Carbon Filtration (removes total chlorine)
- Water Softener (removes Ca, Mg)
- Reverse Osmosis
- Distribution System
- Storage Tank
- Deionization
- Ultraviolet Disinfection
- Final Filtration
- Remote Alarms



Art Work Courtesy of Byron Roshto and Renal Care Group Northwest

Dialysis Water Treatment System

- The dialysis water treatment system is a critical factor in the overall care received by dialysis patients.
- It also poses one of the greatest hazards to the patients if it is not functioning properly.
- Thus, components of the water treatment system must be monitored on a regular basis to ensure proper operation.

Water Testing Schedule[1]

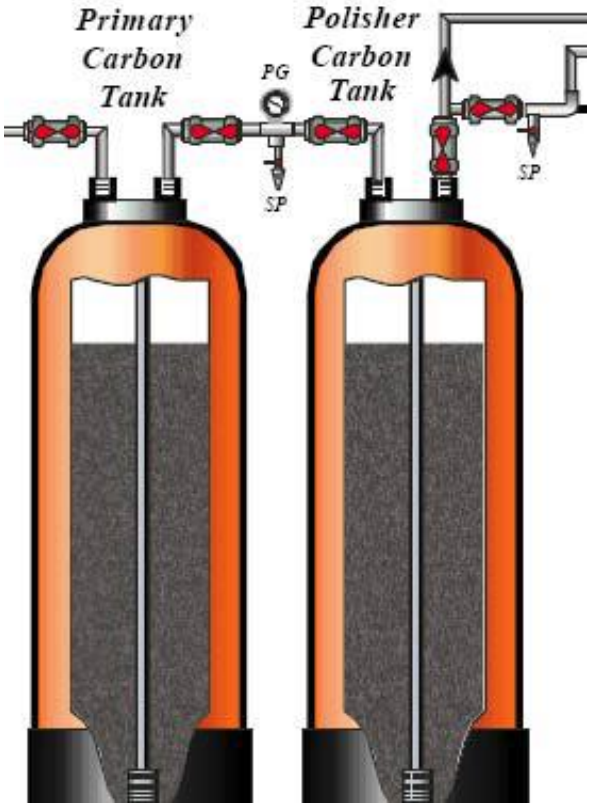
TEST	SAMPLE	MINIMUM FREQUENCY
Total Chlorine (Chloramine)	Post Worker Carbon Post Polisher Carbon Post RO	Per Shift every 4 Hours If Worker Fails, Hourly If Polisher Fails, Hourly
Hardness	Water Softener	Daily
RO Conductivity	RO Product Water	Continuously/Daily Log
DI Resistivity	DI Product Water	Continuously/Daily Log
pH	RO Feed Water	Weekly
Bacteria *	RO Product Water Endo of Loop Reuse Area Water Bicarbonate Solution	Monthly Monthly Monthly Monthly
Endotoxin *	Endo of Loop Reuse Area Water Bicarb Mix Station Water	Monthly Monthly Monthly
*** More often if high levels detected**		

[1] Generally accepted testing guidelines a summarized from AAMI and NANT publications

Testing for Total Chlorine

One of the most critical tasks for patient safety is checking the water for chlorine and chloramines (total chlorine).

- Collect a water sample after the first carbon tank and immediately test for total chlorine concentration.
- If the results are negative, record results and begin dialyzing.
- If the results are positive, take another sample immediately after the water leaves the second tank. *If there is chlorine leaving the second tank, dialysis should be discontinued in the facility.*
- If there is no breakthrough after the second tank, the water can be used but the chlorine level should continue to be monitored after the second tank on an hourly basis until the primary tank is replaced.[2]



[2] *Monitoring Your Dialysis Water Treatment System* - June 2005, Northwest Renal Network - CMS Contract #500-03-NW16

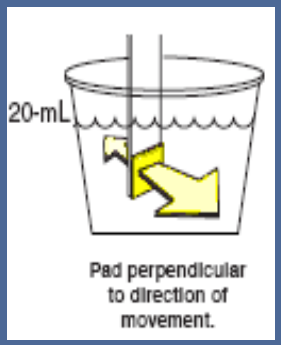
Test for Total Chlorine

HiSENSE ULTRA 0.1™ Test Strips
Product Code 5167

Sensitive enough to meet AAMI standards	• Total chlorine concentration must ≤ 0.1 ppm[3]
Quick results	• Results in 30 seconds
Easy to use; swish & read	• No preparation or mixing of reagents • No calibration or instruments needed • No glass vials or sharps needed

[3] 2011 Association for the Advancement of Medical Instrumentation – ANSI/AAMI/ISO 13959:2009 *Water for hemodialysis and related therapies*

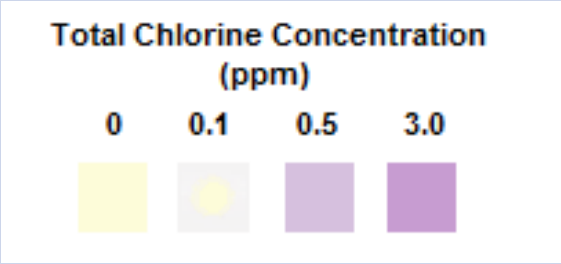
HiSENSE ULTRA 0.1™ Test Strips

Method		
	1. Fill a clean sample cup with the water to be tested, discard contents and re-fill to 20 ml.* 2. Immerse indicator pad into water sample & <u>swish vigorously for 30 seconds</u>.** 3. Remove, shake off excess sample and compare indicator pad to color blocks on bottle label.	

Results

Semi-quantitative

Color blocks at:



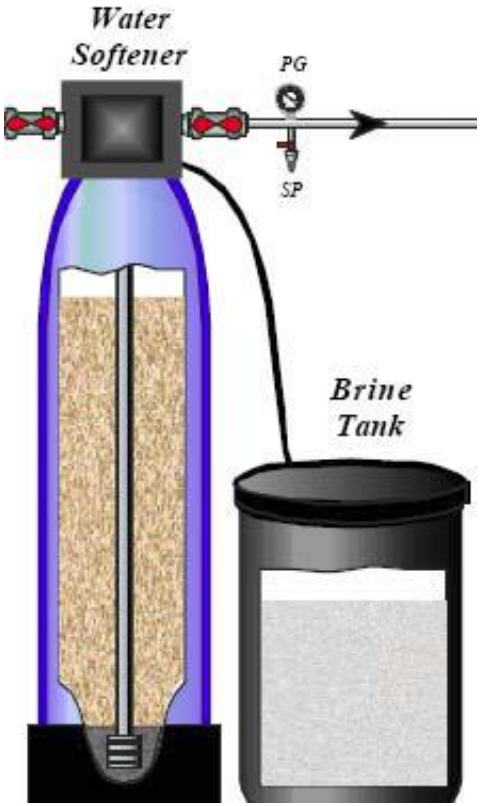
(Diagrams are for illustration purposes only. Please refer to the bottle label & product insert.)

* If there is chlorine in the treated water, the chlorine will react with any organic compound in the container, converting some of the chlorine to inert or less active forms. Initially filling the cup with the water to be tested satisfies the chlorine demand of the container, if any. Collecting and testing a second water sample in the same container will yield a more accurate and stable chlorine concentration when measuring total chlorine.

** When swishing the strip, do so vigorously, but not so forcefully that the pads fall off. Repeatedly hitting the sides of the container when swishing can also cause pads to dislodge.

Testing for Water Hardness

- Water softeners protect and prolong the life of the RO membrane.
- Water softeners also remove calcium and magnesium from the water.
  - Too much calcium or magnesium can cause nausea, vomiting, muscle weakness, severe headaches, skin flushing and low or high blood pressure in a dialysis patient.



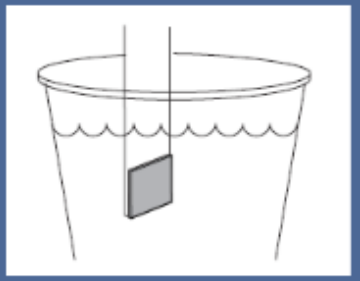
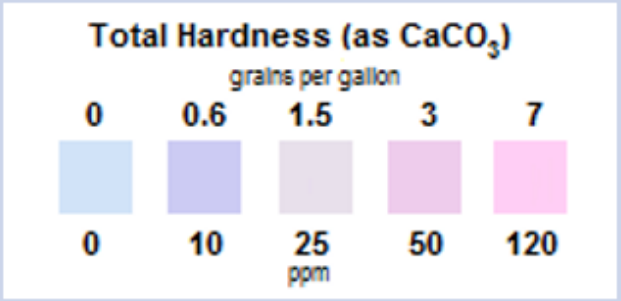
Test for Water Hardness

Water Hardness Test Strips
Product Code 5129

Detects low levels of hardness (as $CaCO_3$)	• Hardness not to exceed 1 GPG (17.24 PPM)[4]
Quick results	• Results in 10 seconds
Easy to use; dip & read	• No preparation or mixing of reagents • No calibration or instruments needed • No glass vials or sharps needed

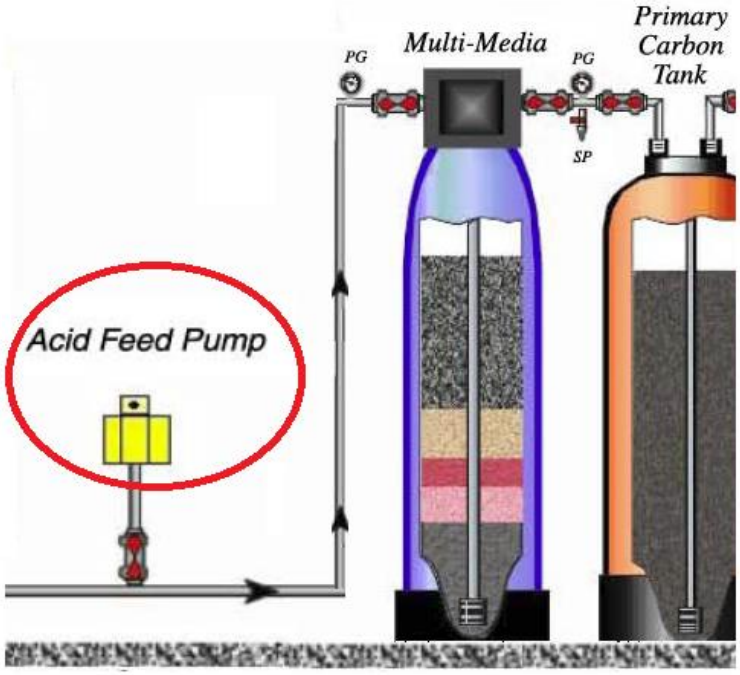
[4]Layman-Amato, R.L., Curtis, J., & Payne, G.M. (2013). Water treatment for hemodialysis: An update. *Nephrology Nursing Journal, 40*(5), 383-404, 465.

Water Hardness Test Strips

Method	1. Properly collect water sample in a clean container. 2. Immerse indicator pad into sample for 1 second and remove. 3. Wait 10 seconds and compare color of indicator pad to color blocks on the bottle label.	
Results	Semi-quantitative Color blocks at:  (Diagrams are for illustration purposes only. Please refer to the bottle label.)	

Testing Water pH

- The pH of incoming water affects:
  - operation of the reverse osmosis (RO) system and
  - the effectiveness of carbon to remove chlorine/chloramines.
- The pH of incoming water should be between 5.0 and 8.5.[4]
- The pH of water post feed pump should be between 7.0 and 8.0.[2]

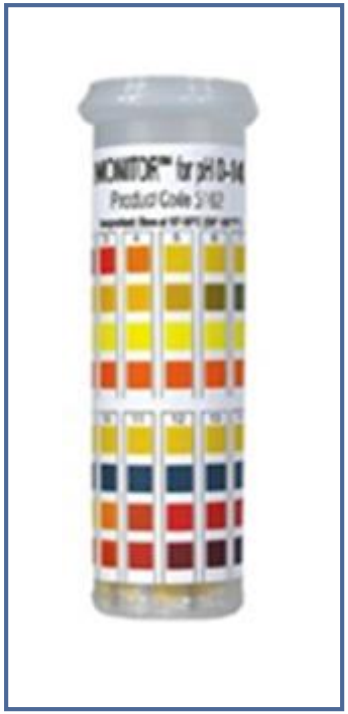


[4] Layman-Amato, R.L., Curtis, J., & Payne, G.M. (2013). Water treatment for hemodialysis: An update. *Nephrology Nursing Journal, 40*(5), 383-404, 465.

[2] *Monitoring Your Dialysis Water Treatment System* - June 2005, Northwest Renal Network - CMS Contract #500-03-NW16

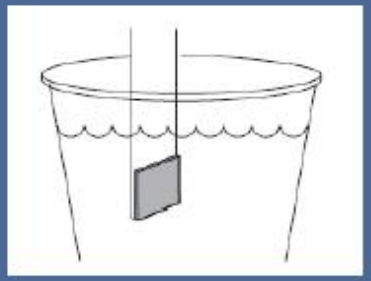
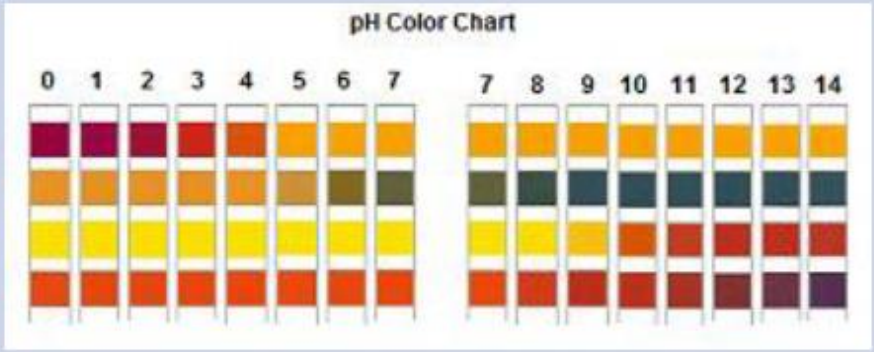
Test for Water pH

Monitor™ for pH 0-14 Test Strips Product Code 5162	
Detects pH of water from 0 to 14 in full pH increments	• pH of incoming water should be between 5.0 and 8.5 [2] • pH of post feed pump water should be of 7- 8
Quick results	• Results in seconds
Easy to use; dip & read	• No preparation or mixing of reagents • No calibration or instruments needed • No glass vials or sharps needed



[2]*Monitoring Your Dialysis Water Treatment System* - June 2005, Northwest Renal Network - CMS Contract #500-03-NW16

Monitor for pH 0-14 Test Strips

Method	1. Properly collect water sample in a clean container. 2. Immerse indicator pads into sample for 1 second and remove. 3. Immediately compare color of indicator pads to color blocks on the bottle label.	
Results	Semi-quantitative Color blocks at:  (Diagrams are for illustration purposes only. Please refer to the bottle label.)	

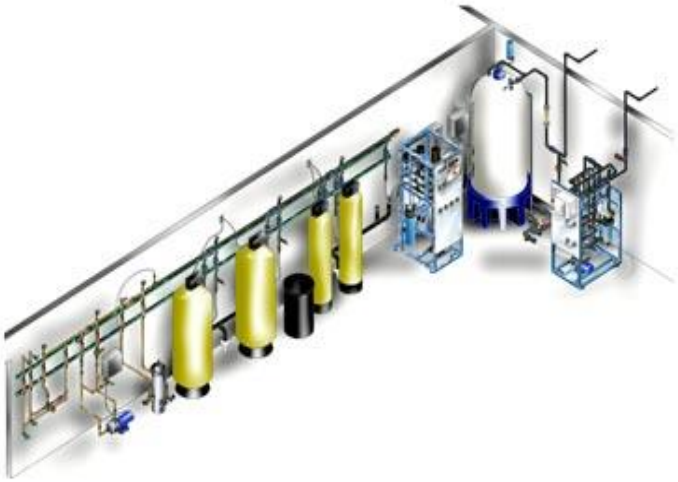
Water System Disinfection

- Water treatment equipment and distribution lines must also undergo routine cleaning and maintenance.

Water System Disinfection

Disinfectants commonly used in water distribution systems include:

- Peracetic acid
- Formaldehyde
- Bleach

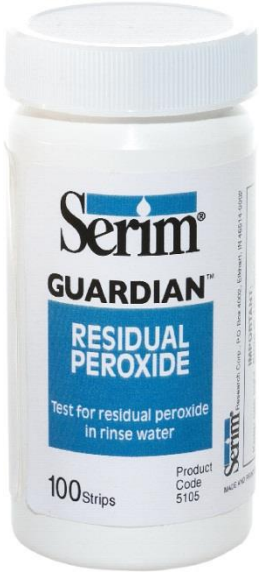


Water System Disinfectant Tests

- After disinfection, always test the equipment and water distribution lines for residual disinfectant before starting dialysis.
- Disinfectant concentrations should be below:

Free chlorine
< 0.5 ppm[3]

Peroxide
<1 ppm[5]



Formaldehyde
<3 ppm[6]

[3] 2011 Association for the Advancement of Medical Instrumentation – ANSI/AAMI/ISO 13959:2009 *Water for hemodialysis and related therapies*

[5] Mar Cor Purification. P/N: 3028402 Rev.B, *Minncare® Cold Sterilant Application Notes*

[6] 2011 Association for the Advancement of Medical Instrumentation – ANSI/AAMI/ISO 26722:2009 *Water treatment equipment for hemodialysis applications and related therapies*

Storing and Handling Test Strips

TIPS:

- Read & follow directions as written in the insert.
- Read results at the time stated. Use a timer; don't estimate.
- To protect test strips from moisture and oxidizing vapors, recap the bottle immediately after removing a strip.
- Do not leave strips laying outside the bottle.
- Do not touch the indicator pad.
- Do not remove the desiccant packet.
- Do not combine strips from one bottle into another bottle.
- Store strips properly; 15°-30°C, store away from heat and sunlight.
- Do not use test strips after the expiration date on the bottom of the bottle.

Testing Technique & Sample Collection

Timing, technique and sample collection affect test strip results.

TIPS:

- The testing technique developed for each test have been optimized to yield accurate and precise results and enhance visual interpretation. Follow directions closely.
- If you receive an ambiguous result, test the sample again.

When testing water:

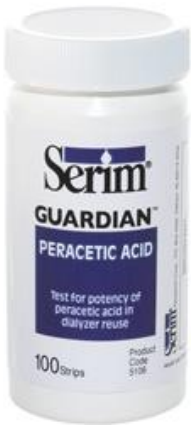
- Let the water system run for 15 minutes before collecting a sample for testing.
- When testing for chlorine in water, test *immediately* after collecting the sample.
- If testing for chlorine produces uncertain results,, obtain a fresh sample before repeating the test. Chlorine is consumed during testing, so retesting the same sample will yield falsely low results.
- Chlorine in water will react with any organic compound in the sample container. The organic material will convert some of the chlorine to inert or less active forms that will not be detected and yield a falsely low result. To get an accurate result when testing for low concentrations of chlorine, satisfy the chlorine demand of the container by filling the container with the water sample, discarding the sample, then collecting a second sample in the same container and testing it for the total chlorine concentration.

GUARDIAN™ Test Strips

TESTS FOR WATER QUALITY			
Product Code	Product	Application	Color blocks at the following levels:
5167	Serim GUARDIAN HiSENSE ULTRA 0.1™ Test Strips	Test for low concentrations of chloramine and/or free chlorine (total chlorine) in post-carbon feed water used to make dialysate. AAMI-suggested maximum - 0.1 ppm	0, 0.1, 0.5 & 3.0 ppm
5109	Serim GUARDIAN HiSENSE™ Test Kit Test Strips	Test for low concentrations of chloramine and/or free chlorine (total chlorine) in post-carbon feed water used to make dialysate. AAMI-suggested maximum 0.1 ppm	Qualitative test PASS: white; <0.1 ppm FAIL: blue; ≥0.1 ppm
5129	Serim GUARDIAN Water Hardness Test Strips	Determination of low levels of hardness (as CaCO3) in feed water and water at the post-softener stage.	0, 10, 25, 50 & 120 ppm
5162	Serim MONITOR for pH 0 –14 Test Strips	Indicates the pH of water or aqueous solutions in the extended range of 0-14.	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14

GUARDIAN™ Test Strips

TESTS FOR EQUIPMENT DISINFECTION			
Product Code	Product	Application	Color blocks at the following levels:
5100A	Serim® GUARDIAN™ Residual Chlorine Test Strips	Test for residual bleach in rinse water after disinfecting dialysis machines. AAMI-suggested maximum 0.5 ppm	0, 0.5, 1, 2 & 5 ppm
5167	Serim GUARDIAN HiSENSE ULTRA 0.1™ Test Strips	Tests for residual bleach in rinse water after disinfecting dialysis machines. AAMI-suggested maximum 0.5 ppm	0, 0.1, 0.5 & 3.0 ppm
5105	Serim GUARDIAN Residual Peroxide Test Strips	Test for residual concentration of peracetic acid/peroxide-based disinfectants in dialyzers after rinsing and/or rinse water after disinfecting HD machines or water distribution lines Industry standard 3 ppm	0, 1, 3, 5 & 10 ppm
5106	Serim GUARDIAN Peracetic Acid Test Strips	Test for effective concentration (potency) of peracetic acid/ peroxide-based disinfectants in reprocessed dialyzers after storage and prior to rinsing.	Qualitative test PASS: PAA >800 ppm FAIL: PAA <400 ppm
5112	Serim GUARDIAN Residual Formaldehyde Test Strips	Test for residual concentration of formaldehyde in dialyzers or portable RO machines after rinsing. AAMI-suggested maximum 3 ppm	0, Trace, 2.5 & 5.0 ppm



GUARDIAN™ Test Strips

TESTS FOR DIALYSATE QUALITY			
Product Code	Product	Application	Color blocks at the following levels:
5116A	Serim GUARDIAN Bicarb pH II Test Strips	Determination of pH in concentrated bicarb solution or final dialysate (acid conc. + bicarb conc. + water)	Final Dialysate: 6.5, 7.0, 7.5, 8.0, 8.5 Bicarb Conc: 8.0, 8.5
5119C	Serim GUARDIAN Blood Leak Test Strips	Confirm the presence or absence of blood in dialysate if a blood leak alarm is activated.	Qualitative test Negative/Positive

Footnotes

1. Generally accepted testing guidelines as summarized from AAMI and NANT publications
2. *Monitoring Your Dialysis Water Treatment System* - June 2005, Northwest Renal Network - CMS Contract #500-03-NW16.
3. 2011 Association for the Advancement of Medical Instrumentation – ANSI/AAMI/ISO 13959:2009 *Water for hemodialysis and related therapies.*
4. Layman-Amato, R.L., Curtis, J., & Payne, G.M. (2013). Water treatment for hemodialysis: An update. *Nephrology Nursing Journal, 40*(5), 383-404, 465.
5. Mar Cor Purification. P/N: 3028402 Rev.B, *Minncare® Cold Sterilant Application Note.*
6. 2011 Association for the Advancement of Medical Instrumentation – ANSI/AAMI/ISO 26722:2009 *Water treatment equipment for hemodialysis applications and related therapies.*

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