

Helping You Meet Industry Guidelines

We provide dialysis facilities the necessary tests to ensure their water quality is in compliance with the latest guidelines established by the Association for the Advancement of Medical Instrumentation (AAMI) and the Centers for Medicare and Medicaid Services (CMS).



Spectra adheres to the most stringent industry testing standards, so you can achieve optimal water quality for your dialysis patients.

Published Guidelines for Bacteriology and Endotoxin Levels

		CMS for ESRD 2008	AAMI RD52:2004	AAMI RD61:2006	AAMI RD62:2006
		Conditions for Coverage ref 42 CFR 494.40	Dialysate for hemodialysis	Concentrates for hemodialysis	Water treatment equipment for hemodialysis applications
Bacteriology					
Water	Allowable limit	<200 CFU/mL			<200 CFU/mL
	Action level	50 CFU/mL			50 CFU/mL
Conventional Dialysate	Allowable limit	<200 CFU/mL	<200 CFU/mL		
	Action level	50 CFU/mL	50 CFU/mL		
Ultrapure Dialysate	Allowable limit	<0.1 CFU/mL	<0.1 CFU/mL		
	Action level	>0.1 CFU/mL	>0.1 CFU/mL		
Bicarbonate	Allowable limit	<200 CFU/mL		<200 CFU/mL	
	Action level	50 CFU/mL		50 CFU/mL	
Endotoxin					
Water	Allowable limit	<2.0 EU/mL			<2 EU/mL
	Action level	1 EU/mL			1 EU/mL
Conventional Dialysate	Allowable limit	<2.0 EU/mL	<2.0 EU/mL		
	Action level	1 EU/mL	1 EU/mL		
Ultrapure Dialysate	Allowable limit	<0.03 EU/mL	<0.03 EU/mL		
	Action level	>0.03 EU/mL	>0.03 EU/mL		
Bicarbonate	Allowable limit	<2.0 EU/mL		<2 EU/mL	
	Action level	1 EU/mL		1 EU/mL	

Education and Support

At Spectra, we make it a point to work side by side with our customers to help them achieve optimal results. We provide:

- Instructions on proper specimen collection, preparation, and handling
- Shipping boxes and sterile containers, specifically designed for water specimens
- Ongoing support from our team of Nephrology Clinical Educators

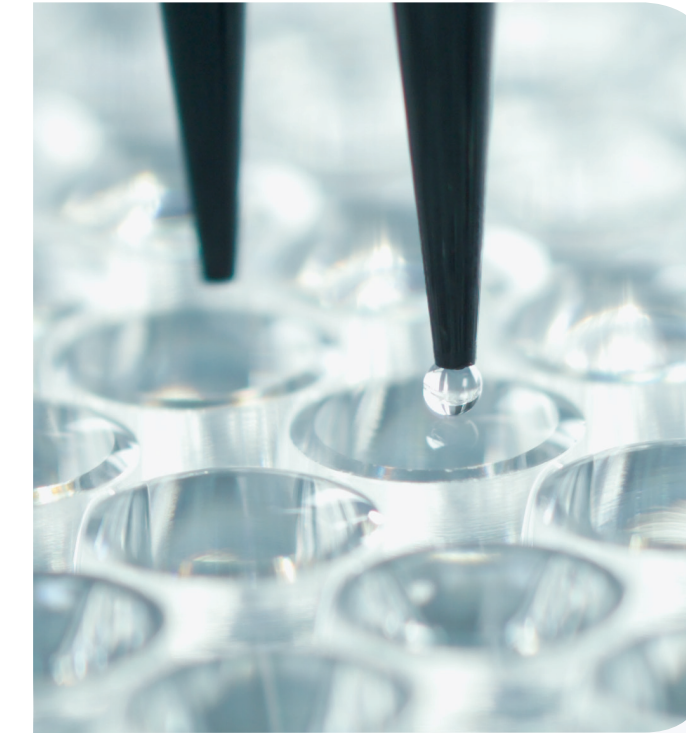
Accreditations and Certifications

Spectra Laboratories adheres to rigorous regulatory standards in the industry through various certifications and accreditations:

- College of American Pathologists (CAP)
- Clinical Laboratory Improvement Amendments (CLIA)
- California Clinical Laboratory License
- New Jersey Clinical Laboratory License
- New York State Environmental Laboratory Approval Program (ELAP)

References

- 1 Ismail N, et al. *Water Treatment for Hemodialysis. Am J Nephrol.* 1996; 16: 60-72.
- 2 Arduino MJ, et al. *Adverse Patient Reactions Due to Chemical Contamination of Hemodialysis Fluids. Dial Transplant.* 1989; 18(12): 655-658.



water & dialysate testing services



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Spectra Laboratories, the leading provider of renal-specific testing services, offers clinicians comprehensive water and dialysate testing to help monitor the safety and efficacy of the dialysis treatments delivered to their patients.

Why Routine Water Testing is Important

Because hemodialysis patients are typically exposed to approximately 400 liters of dialysate each week,^{1,2} the water used to prepare it must be carefully monitored and controlled on a regular basis to ensure the highest quality.

Our Tests are Designed to Help You

- Monitor the effectiveness of your facility's water treatment system
- Identify contaminants that may compromise patient care
- Comply with federal regulations for dialysis water quality



Water quality is critical to safe dialysis treatment.

Helping to Keep Your Patients Safe

We recognize that even the low levels of chemicals, bacteria, and endotoxins found in municipal water, if transferred to dialysate, may be hazardous to dialysis patients.^{1,2} That's why we provide state-of-the-art water testing services to help safeguard your patients.

Comprehensive Water & Dialysate Testing

Spectra offers a wide range of tests including:

Trace Elements

- Aluminum
- Antimony
- Arsenic
- Barium
- Beryllium
- Cadmium
- Calcium
- Chromium
- Copper
- Fluoride
- Iron
- Lead
- Magnesium
- Mercury
- Nickel
- Nitrate
- pH
- Phosphorus
- Potassium
- Resistivity
- Selenium
- Silver
- Sodium
- Sulfate
- Thallium
- Zinc

Total Viable Microbial Count

- Bicarbonate
- Dialysate
- Reuse Sterile Dialyzer Fluid
- Water

Endotoxin (LAL) Detection

- Bicarbonate
- Conventional and Ultrapure Dialysate
- Water

Expertise You Can Rely On

Our Clinical Laboratory Scientists have years of laboratory experience, training, and knowledge to ensure proper handling of your specimens.

State-of-the-Art Analysis Methods

At Spectra, we invest in the latest technologies and cutting-edge instrumentation for accurate results and faster turnaround times.

Specimens are promptly processed upon arrival at the laboratory

- **Trace Elements**
 - Dual Channel Ion Chromatography System (ICS)
 - Inductively Coupled Plasma Mass Spectroscopy System (ICP-MS)
- **Total Viable Microbial Count**
 - Heterotrophic Plate Count (HPC) spread plate technique
- **Endotoxin (LAL) Detection**
 - Kinetic Quantitative Chromogenic Test
 - High throughput automated pipettor
 - Incubating plate reader

Web-based Results

Spectra delivers timely, reliable results, so you have the information you need to make timely decisions regarding your facility's water treatment system and your patient's care.

