



water & dialysate testing

Helping You Meet Federal Guidelines

We provide dialysis facilities the necessary tests to ensure their water quality is in compliance with the latest guidelines established by the American Association for the Advancement of Medical Instrumentation (AAMI) and the Center 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 Bacteria and Endotoxin Levels

		CMS RD5:1995	AAMI RD61:2001	AAMI RD62:2001	AAMI RD52:2004
Water (Bacteria count)	Abnormal	>200 CFU/mL	n/a	>200 CFU/mL	>200 CFU/mL
	Action Level	n/a	n/a	>50 CFU/mL	>50 CFU/mL
Bicarbonate (Bacteria count)	Abnormal	>200 CFU/mL	>200 CFU/mL	n/a	>200 CFU/mL
	Action Level	n/a	n/a	n/a	>50 CFU/mL
Dialysate (Bacteria count)	Abnormal	>2000 CFU/mL	n/a	n/a	>200 CFU/mL
	Action Level	n/a	n/a	n/a	>50 CFU/mL
Water or Dialysate (Endotoxin detection)	Abnormal	>5.0 EU/mL	>2.0 EU/mL	>2.0 EU/mL	>2.0 EU/mL
	Action Level	n/a	n/a	>1.0 EU/mL	>1.0 EU/mL

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 300-400 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

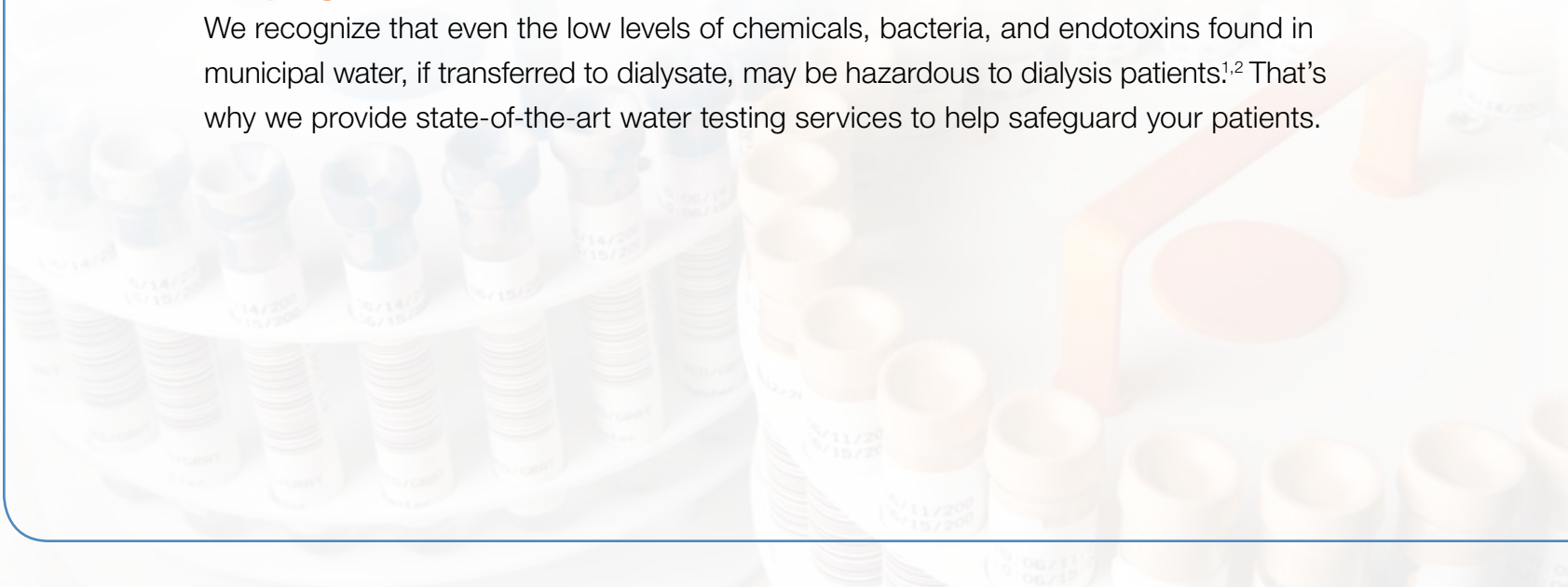
- Monitor the effectiveness of your facility's water treatment system
- Identify contaminants that may compromise patient care
- Comply with federal regulations for dialysis water quality



Water quality is critical to safe dialysis treatment.

Keeping 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

Bacteria Count

- Bicarbonate
- Dialysate
- Water
- Reuse Sterile Dialyzer Fluid

Endotoxin (LAL) Detection

- Dialysate
- Water
- Bicarbonate

Ultrapure Testing for Home Hemodialysis*

- Bacteria (membrane filtration)
- Endotoxins

**Spectra's ultrapure testing methods are used to monitor dialysate samples in which bacterial and endotoxin levels must be significantly lower than the standards established by AAMI guidelines RD52:2004.*

Proper Specimen Collection and Handling

Quality results begin with quality collection and handling techniques. Spectra provides comprehensive written instructions and visual aids to assist in the proper collection and handling of specimens before they reach the laboratory for analysis.

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 immediately processed upon arrival at the laboratory

- **Trace Elements**
 - Dionex® ICS-600 (dual channel ion chromatography system)
 - Agilent 7500 ce ICP-MS (inductively coupled plasma mass spectroscopy system)
- **Bacterial Counts**
 - Spread plate technique
 - Membrane filtration
 - Automated colony count reader
- **Endotoxin (LAL) Detection**
 - Kinetic chromogenic test
 - Tecan® Freedom EVO® automated pipettor
 - Incubating spectrophotometer



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.

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
- Sterile containers, specially designed for water testing
- Ongoing consultation from our team of clinical laboratory specialists

Accreditations and Certifications

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

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- 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.

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