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).

Published Guidelines for Bacteriology and Endotoxin Levels

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Water</td>
<td>&lt;200 CFU/mL</td>
<td>&lt;200 CFU/mL</td>
<td>&lt;200 CFU/mL</td>
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<tr>
<td>Action Level</td>
<td>50 CFU/mL</td>
<td>50 CFU/mL</td>
<td>50 CFU/mL</td>
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<tr>
<td>Conventional Dialysate</td>
<td>&lt;200 CFU/mL</td>
<td>&lt;200 CFU/mL</td>
<td>&lt;200 CFU/mL</td>
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<tr>
<td>Action Level</td>
<td>50 CFU/mL</td>
<td>50 CFU/mL</td>
<td>50 CFU/mL</td>
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<tr>
<td>Ultrapure Dialysate</td>
<td>&lt;0.1 CFU/mL</td>
<td>&lt;0.1 CFU/mL</td>
<td>&lt;0.1 CFU/mL</td>
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<tr>
<td>Action Level</td>
<td>&lt;0.1 CFU/mL</td>
<td>&lt;0.1 CFU/mL</td>
<td>&lt;0.1 CFU/mL</td>
</tr>
<tr>
<td>Bicarbonate</td>
<td>&lt;200 CFU/mL</td>
<td>&lt;200 CFU/mL</td>
<td>&lt;200 CFU/mL</td>
</tr>
<tr>
<td>Action Level</td>
<td>50 CFU/mL</td>
<td>50 CFU/mL</td>
<td>50 CFU/mL</td>
</tr>
</tbody>
</table>

| Water                  | <2 EU/mL      | <2 EU/mL       |
| Action Level           | 1 EU/mL       | 1 EU/mL        |
| Conventional Dialysate | <2 EU/mL      | <2 EU/mL       |
| Action Level           | 1 EU/mL       | 1 EU/mL        |
| Ultrapure Dialysate    | <0.05 EU/mL   | <0.05 EU/mL    |
| Action Level           | <0.05 EU/mL   | <0.05 EU/mL    |
| Bicarbonate            | <2 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
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, 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

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

**Total Viable Microbial Count**
- Bicarbonate
- Dialysate
- Reuse Sterile Dialyzer Fluid
- Conventional and Ultrapure Dialysate
- Water

**Endotoxin (LAL) Detection**
- Bicarbonate
- 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.