## **Colony Count and LAL Testing**

Ascend Clinical is one of the leading providers of dialysis laboratory testing and services to healthcare clinics across the United States.

## **Colony Count Testing**

Ascend offers Colony Count RD52, RD62 and Colony Count AAMI/ISO for two source types:

Dialysate and Dialysis Water.

Colony Count RD52, RD62	<ul> <li>Meets the minimal standards required by CMS with a maximum allowable limit of 200 cfu/mL.</li> </ul>
Colony Count AAMI/ISO	<ul> <li>Follows the most recent AAMI guidelines which have a maximum allowable limit of 100 cfu/mL.</li> </ul>
	The lower maximum limit increases:
	<ul> <li>The number of samples that reach this threshold, requiring additional reagents and culture dishes.</li> </ul>
	The frequency of secondary reviews performed by an Environmental Analyst.
	<ul> <li>This new threshold is also endorsed by accreditation organizations such as the Joint Commission (formerly JCAHO) and NDAC (National Dialysis Accreditation Commission).</li> </ul>
NY Colony Count Testing	<ul> <li>In addition to the above standards, the state of New York requires all samples to be run in duplicate.</li> </ul>

## **LAL Testing**

Ascend offers LAL Endotoxin, LAL Dialysate (ISO), and LAL Water (ISO) for source type dialysate and dialysis water, respectively.

LAL Endotoxin	<ul> <li>Meets the minimal standards required by CMS with a maximum allowable limit of 2 EU/mL.</li> </ul>
LAL Dialysate (ISO) and LAL Water (ISO)	<ul> <li>Follows the most recent AAMI guidelines which have a maximum allowable limit of 0.5 EU/mL for dialysate and 0.25 EU/mL for water.</li> <li>This lower maximum limit requires batching ISO samples separately to avoid the possibility of a false positive resulting from sample dilution.</li> <li>This process requires a manual review by an Environmental Analyst, segregation of ISO samples, and a re-run on a different instrument prior to releasing the results.</li> </ul>

