eurofins | Medical Device Testing



Bacterial Endotoxin Testing/ LAL

The most common pyrogen found in medical devices, Endotoxins can pose significant risk to patients. If left undetected, high levels of endotoxins can enter into the blood stream through a medical device, causing adverse reactions such as hemorrhagic shock, diarrhea, meningitis, fever, altered resistance to bacterial infection, a rapid drop in blood pressure, and numerous other severe biological effects.

The Bacterial Endotoxin test, also known as Limulus Amebocyte Lysate (LAL), is necessary to quantify this gram-negative bacteria within a cell wall. Performed as a lot release test, the LAL assesses medical devices coming in contact with cerebrospinal fluid or the cardiovascular system. This determines the presence of bacterial endotoxins by testing the blood cells of horseshoe crabs to identify pyrogenic responses.

Any product that comes in direct or indirect contact with intravascular, intralymphatic, intrathecal and/ or intraocular systems, must undergo bacterial endotoxin testing (LAL) to confirm that the product's endotoxin content is below the allowable release limit of 0.5 EU/mL.

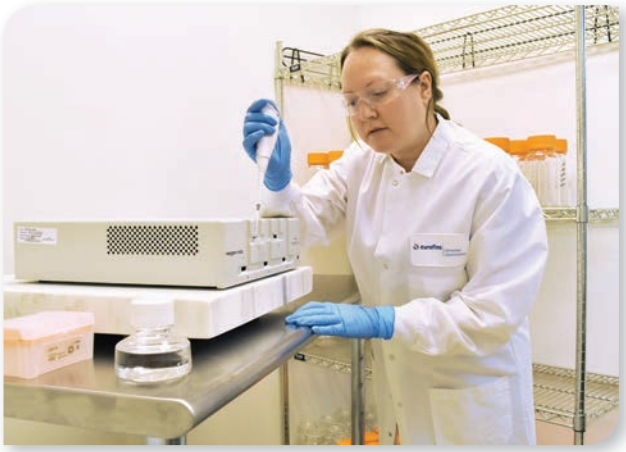
Choose Eurofins Medical Device Testing to help you:

- Understand Bacterial Endotoxin/LAL Testing
- Meet regulatory requirements for USP Chapter <85>
- Select the most appropriate method for your specific product
- Ensure the safety of every lot released

Reference Methods

Our testing methods follow the most current requirements outlined in:

- AAMI ST72
- USP/NF <161><85>
- Ph Eur 2.6.14 Method D



LAL Testing Panel

- **Gel Clot:** Equal amounts of test sample and the gel clot LAL are mixed in a tube and incubated. After incubation, the tube is inverted. If endotoxin is present, the solution will clot and the gel will remain at the bottom of the tube.
- **Kinetic Turbidimetric**: A tube reader or 96 well plate reader monitors the change in a solution's clarity as a result of the presence of endotoxin. The faster the solution changes, the more endotoxin in the test sample. The reaction time of the sample is compared to a standard curve to calculate endotoxin concentration.
- **Kinetic Chromogenic:** Monitors the change in a solution's color. More endotoxin means the solution will turn yellow faster. A fixed time frame and intensity of color is used to distinguish the endotoxin level.