Rapid, Accurate Endotoxin Testing Available

The Bioexpression and Fermentation Facility (BFF) now offers endotoxin testing with USP/BET compliant methods using the Endosafe Nexgen-PTS™ system.

Endotoxins are lipopolysaccharides (LPS) from the outer membrane of gram-negative bacteria. Contamination from endotoxin is a common problem for products like nucleic acids and recombinant proteins produced in *E. coli*. Contamination affects mammalian cells in culture and in vivo, and can lead to dangerous outcomes like shock, inflammation or sepsis in animal models.

The Limulus amebocyte lysate (LAL) assay is the gold standard for detection and quantification of endotoxin. Endotoxin is recognized by the primitive amebocytes of the Atlantic horseshoe crab (*Limulus polyhemos*). When the cells encounter endotoxin, a cascade of events occur at the molecular level that result in the formation of defensive clots. Less than one billionth of a gram of endotoxin can be qualitatively assessed.

The LAL assay has historically been offered with gel-clot, turbidimetric or chromogenic readouts that consume large amounts of costly reagents. With each assay a standard curve and an assessment of interfering substances must be completed, along with replicates and dilutions of the test sample. This traditional format is time-consuming and often suffers from user variability.

The BFF offers testing of samples with minimum assay volumes of 25 microliters which is 20 times less than traditional testing. Each sample is tested in duplicate with a positive control against an archived standard curve. This methodology reduces variability between analysts and allows correlation coefficients to be calculated from a statistically sound number of points for a 2 log standard curve. Results are returned within 48 hours of receipt of samples.