Endotoxin Detection Assay based on ELISA-technology and Recombinant Factor C (rFC)

EndoLISA® is a quantitative fluorescence end-point assay for highly specific and robust endotoxin testing. The assay is based on high-affinity binding through an endotoxin specific bacteriophage-derived protein coated onto micro-plate wells and recombinant Factor C (rFC) for detection.

With its unique built-in sample preparation, **EndoLISA®** revolutionizes endotoxin testing; the selective microplate enables an efficient wash step removing interfering substances prior to the enzymatic detection reaction with rFC. **EndoLISA®** offers precise and robust quantification of the endotoxin content in complex pharmaceutical, biological and environmental samples, less matrix effects and with a very broad measurement range.

EndoLISA® at a Glance

- Overcomes limitations of conventional methods such as inhibition and enhancement
- Endotoxin specific, no false-positive results from ß-Glucans
- Highly robust method and excellent lot-to-lot reproducibility
- Broad measurement range (0.05-500 EU/ml, pH4-pH9)
- Animal-free method relying on sustainable resources
- Methodology is included in the European Pharmacopoeia Chapter 5.1.10, Section 9. Removal of Interfering Factors
- Validated according to standard Bacterial Endotoxin Testing (BET) criteria

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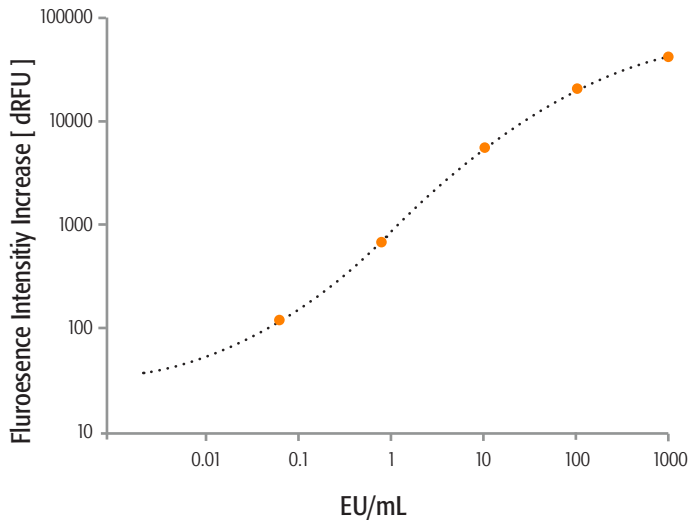
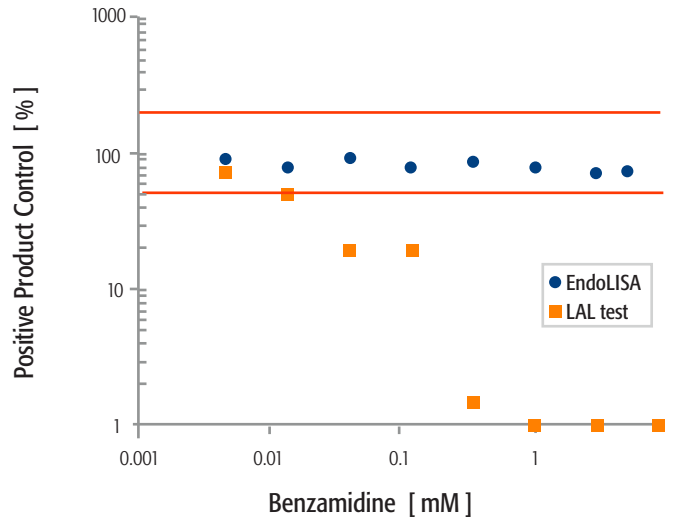


EndoLISA® Standard Curve

A typical standard curve of the **EndoLISA®** assay using a non-linear 4-parameter logistic function; concentrations of the CSE (Control Standard Endotoxin) are plotted against the relative fluorescence signal.



EndoLISA® Performance

EndoLISA's wash step offers the advantage of removing interfering sample components compared to LAL. Here the advantage is demonstrated by the PPC recovery (Positive Product Control) in relation to the increasing concentration of benzamidine (an enzyme inhibitor, inhibiting the Factor C reactions in LAL and rFC-based methods). The red lines denote the Pharmacopoeia criteria of a valid PPC recovery of 50–200 %.

EndoLISA® Kit Components

Cat. No. 609033, 192 Tests
All reagents needed for running the assay are included in the kit:

EndoLISA® Plates (pre-coated microplates; a total of 12 modules with 16 wells each), Endotoxin Standard CSE (*E. coli* O55:B5), Binding Buffer, Enzyme rFC, Substrate, Assay Buffer, Wash Buffer, Water free of detectable levels of endotoxin, Cover foil

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