

Recombinant Factor C (rFC) Endotoxin Detection Assay

Fluorescence end-point assay for highly specific bacterial endotoxin testing

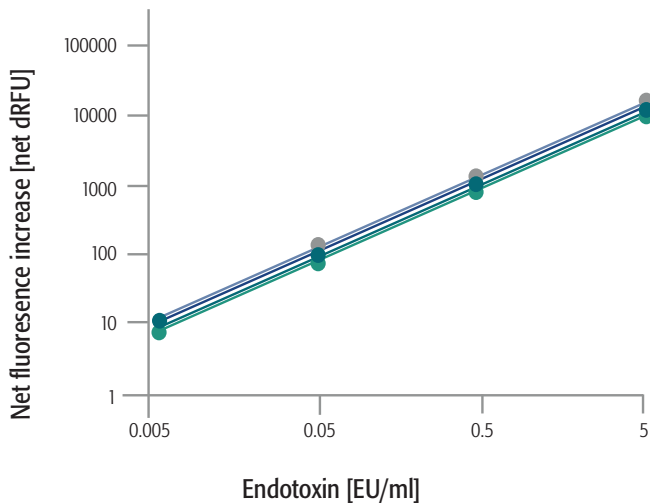
The **EndoZyme® II** assay is the enhanced second generation of **EndoZyme®**, based on recombinant Factor C (rFC), the synthetic analogue to the native endotoxin-specific principal receptor in the Limulus Amebocyte Lysate (LAL) cascade. Instead of being based on an animal source, **EndoZyme® II** is a sustainable alternative method in line with regulatory requirements.

With an assay range of 0.005 to 50 EU/ml and 60 minute assay time, **EndoZyme® II** offers state-of-the-art test performance by specifically detecting endotoxin, but also overcoming the common issue of false-positive results with LAL due to β -Glucans. The fast and easy-to-use **EndoZyme® II** assay is particularly suited for end-product testing and in-process control of water and raw materials as well as medical device testing.



EndoZyme® II at a Glance

- Animal-free method relying on sustainable resources
- State-of-the-art sensitivity (0.005 EU/ml) and assay range
- Endotoxin-specific, no false-positive results from β -Glucans
- Excellent lot-to-lot reproducibility
- Stable liquid reagents enabling flexibility in use
- Follows BET methodology and validated according to the same criteria as conventional methods
- Accepted by the FDA and included in the European Pharmacopoeia Chapter 5.1.10 since 2016

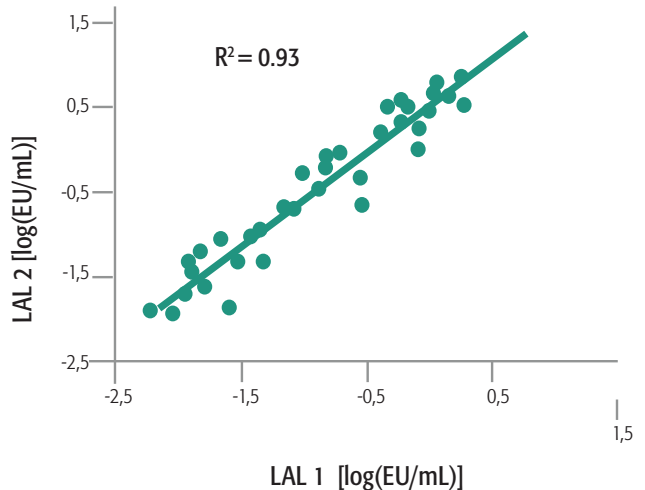
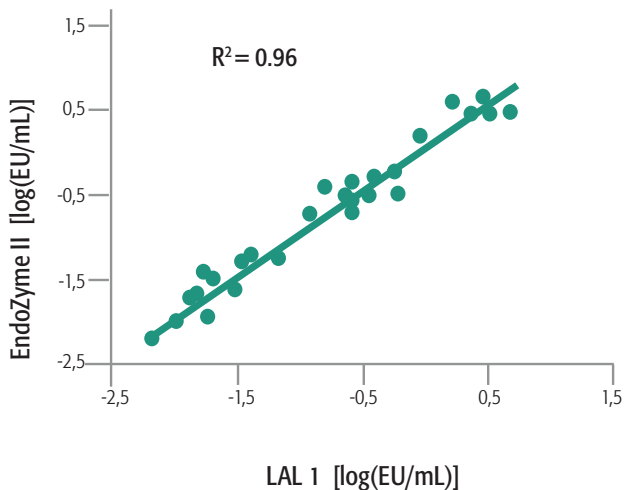


EndoZyme® II Standard Curves/Lot-to-Lot Consistency

Standard curves from 5 different **EndoZyme® II** lots applying linear regression; concentrations of the CSE (Control Standard Endotoxin) are plotted against the net relative fluorescence signal increase.

EndoZyme® II Correlation with LAL tests

EndoZyme® II and two different LAL tests were compared in terms of determined concentrations of 30 different endotoxin samples. The correlation between **EndoZyme® II** and LAL Supplier 1 was shown to be higher ($R^2 = 0.96$) than the correlation between LAL Supplier 1 and LAL Supplier 2 ($R^2 = 0.93$).



EndoZyme® II Kit Components

Cat. No. 890030, 192 Tests

All reagents needed for running the assay are included in the kit:

Enzyme Recombinant Factor C (rFC), Endotoxin Standard CSE (*E. coli* O55:B5), Substrate, Assay Buffer, Water free of detectable levels of endotoxin, Assay Plates

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