



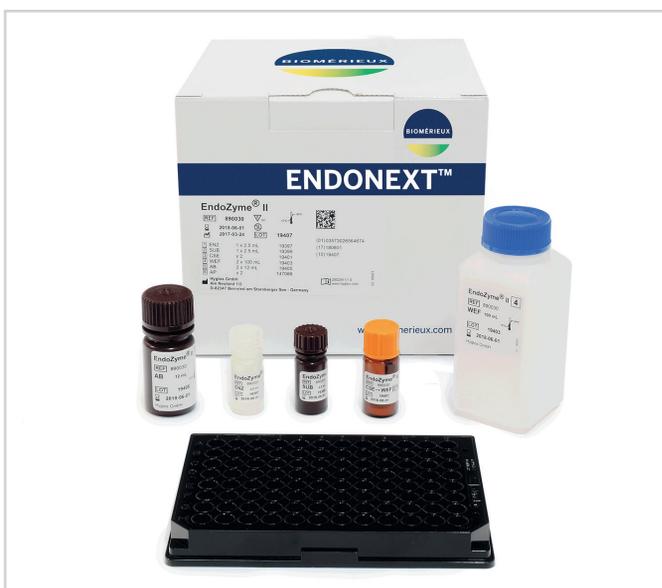
ENDOZYME® II

Recombinant Factor C (rFC) Endotoxin Detection Assay

Fluorescence end-point assay for highly specific bacterial endotoxin testing:

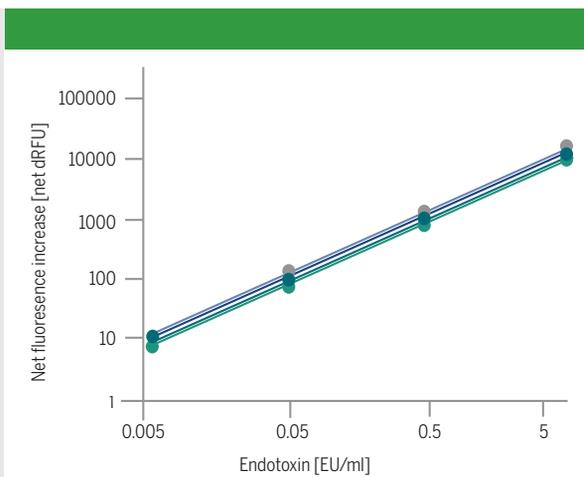
The ENDOZYME® II assay is the enhanced second generation of ENDOZYME® II, based on recombinant Horseshoe Crab Factor C (rFC), the synthetic analogue to the native endotoxin-specific principal receptor in the Limulus Amebocyte Lysate (LAL) cascade. Instead of being based on an animal source, ENDOZYME®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

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

- Sustainable rFC eliminates the need to harvest horseshoe crabs for their blood
- State-of-the-art sensitivity (down to 0.001 EU/mL)
- 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

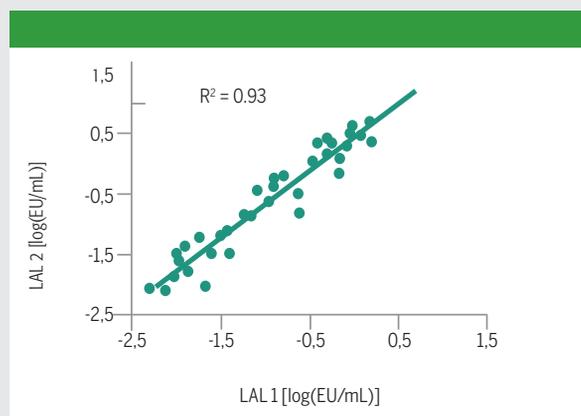
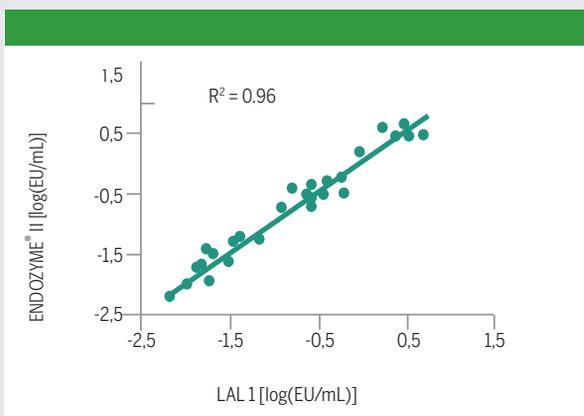


ENDOZYME® II STANDARD CURVES/ LOT-TO-LOT CONSISTENCY

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 192 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

Cat. No. 423129, 3072 Tests (bulk)

The bulk kit contains: Enzyme Recombinant Factor C (rFC), Endotoxin Standard CSE (E. coli O55:B5), Substrate and Assay Buffer.

Supplied separately: Water free of detectable levels of endotoxin, Assay plates