

Endotoxin Detection Assays

EndoZyme®

EndoZyme® is a homogeneous fluorescence end-point assay for the quantitative determination of endotoxins (lipopolysaccharides). The assay is based on an improved recombinant Factor C (rFC), the endotoxin-specific principal receptor in the LAL enzyme cascade. With a dynamic range of 0-50 EU/ml and a sensitivity of 0.005 EU/ml, EndoZyme® offers state-of-the-art test performance.

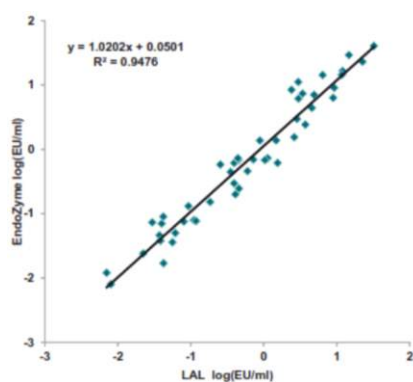
EndoZyme® specifically detects endotoxin thereby overcoming the problem with false-positive results due to β -Glucans. EndoZyme® is particularly suited as endotoxin test for biopharmaceuticals, medical devices, water and environmental swabs.

Better Alternative
to LAL Test



Recommended as LAL alternative in EU & US Pharmacopoeia
(EP,5.1.10) & (USP33,NF28,6.30)

EndoZyme® endotoxin detection standard curve

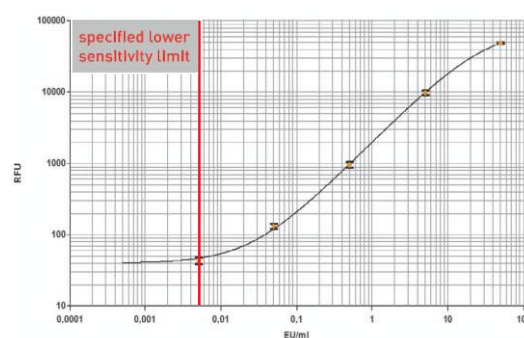


Correlation plot of EndoZyme® versus LAL assay where multiple LPS preparations and dilutions from different bacteria such as E. coli, Salmonella and Pseudomonas, including LPS of mutant strains, were compared. The endotoxin was determined quantitatively according to the manufacturer's instructions and the results (EU/ml) were plotted against each other. This comparison shows that EndoZyme® correlates well with the commercially available LAL test, with a correlation coefficient (R2) of 0.9476.

Specifications & Advantages

- Highly sensitive endotoxin detection assay
- Broad measurement range 0.005-50 EU/ml
- LPS-specific recombinant technology
- No false-positive β -Glucan reaction
- Excellent reliability and lot-to-lot consistency
- All needed reagents included in the kit
- No animal material, therefore saving the diminishing horseshoe crab population

EndoZyme® correlation with LAL-Assay



Standard curve of the EndoZyme® Assay; concentrations of the LPS standard are plotted against the corresponding relative fluorescence signal. The log net fluorescence is proportional to the log endotoxin concentration and is linear in the 0.005-50 EU/ml range

Kit Components

EndoZyme® - 192 tests (Cat No. 609050)

- | | |
|-------------------------|------------------------|
| • Fluorogenic Substrate | • Recombinant Factor C |
| • Endotoxin-free water | • Endotoxin Standard |
| • Assay Plates | • Assay Buffer |

EndoLISA®

EndoLISA® is a new method for determination of endotoxin (LPS) levels where high-affinity binding of endotoxin by LPS-specific phage protein is followed by endpoint fluorescence measurement.

The microtiter plate -based assay format is one of the major advantage of EndoLISA®, as a result of which potentially interfering substances such as organic solvents, chaotropic substances and detergents are removed by a washing step. This enables the EndoLISA® user to precisely determine the endotoxin level without matrix effects, without the need for dilution and with a very broad measurement range.

Better Alternative
to LAL Test

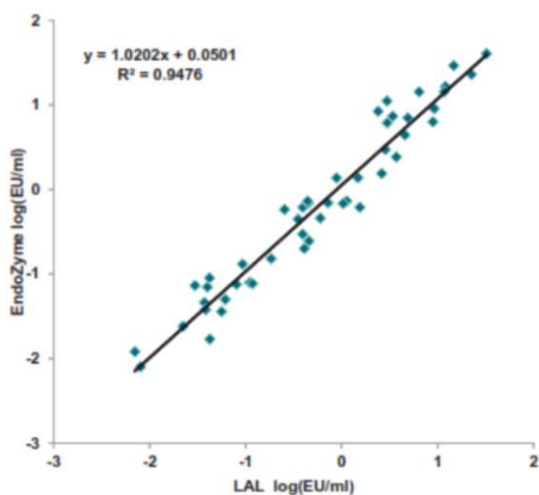


Recommended as LAL alternative in EU & US Pharmacopoeia
(EP,5.1.10) & (USP33,NF28,6.30)

Specifications & Advantages

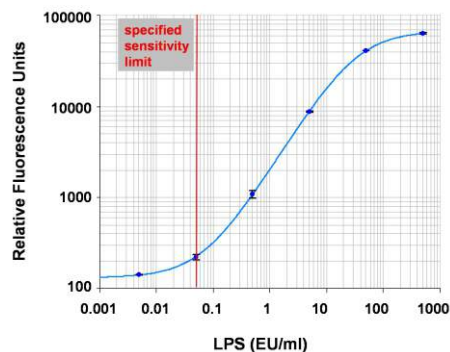
- Overcomes limitations of existing methods, such as the need for extension dilution
- Reduced matrix effects due to integrated washing step
- Robust assay with excellent reproducibility
- Broad measurement range (0.05-500 EU/ml)
- Broad pH range (pH4 - pH9)
- Less interference at high salt conditions e.g. NaCl, GdnHCl
- All reagents necessary to run the assay included in the kit
- Saves the diminishing horseshoe crab population

EndoZyme® endotoxin detection standard curve



Correlation plot of EndoLISA® versus LAL assay where multiple LPS preparations and dilutions from different bacteria such as E. coli, Salmonella and Pseudomonas, including LPS of mutant strains, were compared. The endotoxin was determined quantitatively according to the manufacturer's instructions and the results (EU/ml) were plotted against each other. This comparison shows that EndoLISA® correlates well with the commercially available LAL -assay, with a correlation coefficient of 0.9078.

EndoZyme® correlation with LAL-Assay



Standard curve of the EndoLISA® test; concentrations of the LPS standard are plotted against the relative fluorescence signal. EU, endotoxin unit.

Kit Components

EndoLISA®- 192 tests (Cat No. 609033)

- | | |
|--------------------------------|-----------------------|
| • Pre-coated microtiter plates | • Enzyme |
| • Endotoxin-free water | • Substrate |
| • Binding Buffer | • Assay & Wash Buffer |
| • Endotoxin Standard | • Cover foils |

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