

EndoZyme® II GO

Fast 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.

The rapid GO version of EndoZyme® II features GOPLATE™ - a microplate pre-filled with dried Control Standard Endotoxin, standard curve 0.005 - 50 EU/ml and Positive Product Controls (PPC) 0.5 EU/ml, all in duplicate replicates fulfilling pharmacopoeia standard curve requirements.

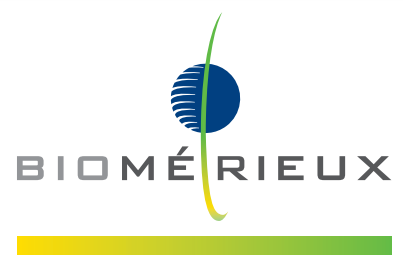
This new version of EndoZyme® enables endotoxin testing in pharmaceutical grade water, injectable drugs and other pharmaceutical products. EndoZyme® II GO allows an easy and fast workflow, and is particularly adapted to raw materials and final product testing.

EndoZyme® II : YUhi fYg

- Horseshoe Crab
- Assay run time: 20 minutes (0.05 EU/ml), 60 minutes (0.005 EU/ml)
- Preloaded microplate eliminates manual preparation of standard dilutions and PPCs
- Over 50% reduction in handling time compared to conventional microplate assays
- Significantly reduces risk of handling error during preparation steps
- Higher precision and rate of valid results
- Ideal for in-process control of water and raw materials as well as product release testing
- Ideal for automation and parallel processing of plates

EndoZyme® II ; C`6 YbYZhg

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GOPLATE™ layout

The GOPLATE™ is pre-loaded with Control Standard Endotoxin (CSE) as follows:

STD = Control Standard Endotoxin (CSE),
e.g. STD 50 = 50 EU/ml

BLK = blank, empty well

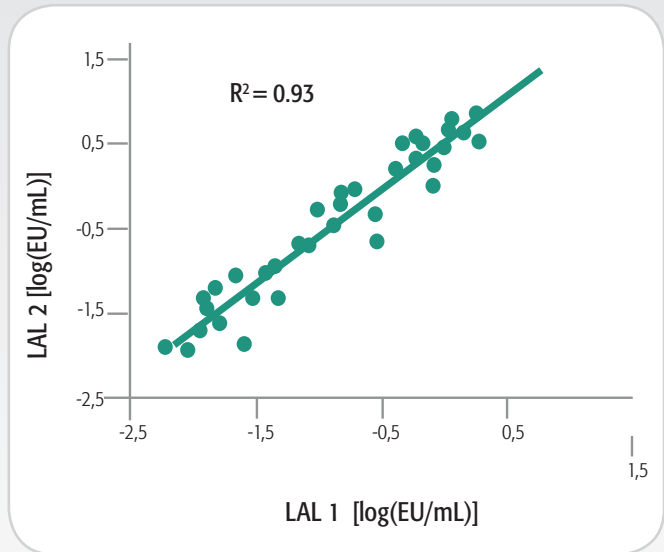
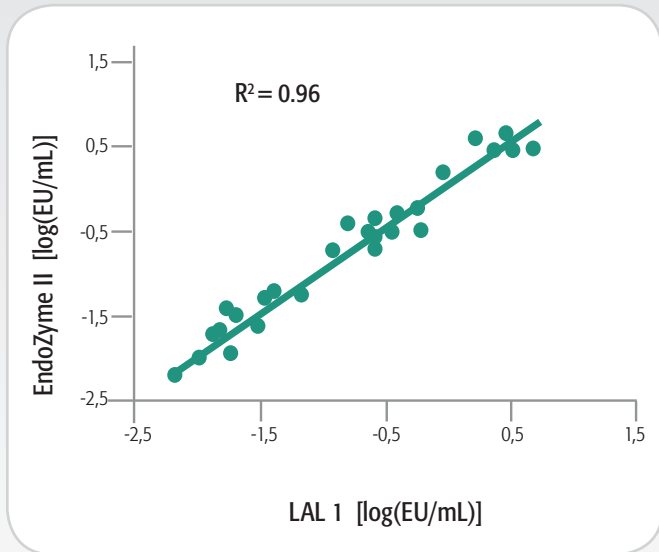
PPC = Positive Product Control
(= 0.5 EU/ml)

SPL = sample, empty well

	1	2	3	4	5	6	7	8	9	10	11	12
A	STD 50	STD 50	PPC SPL 1	PPC SPL 2	PPC SPL 3	PPC SPL 4	PPC SPL 5	PPC SPL 6	PPC SPL 7	PPC SPL 8	PPC SPL 9	PPC SPL 10
B	STD 5	STD 5	PPC SPL 1	PPC SPL 2	PPC SPL 3	PPC SPL 4	PPC SPL 5	PPC SPL 6	PPC SPL 7	PPC SPL 8	PPC SPL 9	PPC SPL 10
C	STD 0.5	STD 0.5	SPL 1	SPL 2	SPL 3	SPL 4	SPL 5	SPL 6	SPL 7	SPL 8	SPL 9	SPL 10
D	STD 0.05	STD 0.05	SPL 1	SPL 2	SPL 3	SPL 4	SPL 5	SPL 6	SPL 7	SPL 8	SPL 9	SPL 10
E	STD 0.005	STD 0.005	SPL 11	SPL 12	SPL 13	SPL 14	SPL 15	SPL 16	SPL 17	SPL 18	SPL 19	SPL 20
F	BLK	BLK	SPL 11	SPL 12	SPL 13	SPL 14	SPL 15	SPL 16	SPL 17	SPL 18	SPL 19	SPL 20
G	BLK	BLK	PPC SPL 11	PPC SPL 12	PPC SPL 13	PPC SPL 14	PPC SPL 15	PPC SPL 16	PPC SPL 17	PPC SPL 18	PPC SPL 19	PPC SPL 20
H	PPC Control	PPC Control	PPC SPL 11	PPC SPL 12	PPC SPL 13	PPC SPL 14	PPC SPL 15	PPC SPL 16	PPC SPL 17	PPC SPL 18	PPC SPL 19	PPC SPL 20

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 GO Kit Components

Cat. No. 890031, 192 Tests

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

Enzyme Recombinant Factor C (rFC), Preloaded GOPLATE Assay Plates, Substrate, Assay Buffer, Water free of detectable levels of endotoxin.

Authorized Distributor:

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