

The Next Generation of Recombinant Endotoxin Testing Recombinant Cascade Kinetic-Chromogenic Assay (rCKA)

Designed for a seamless transition from conventional LAL testing to animal-free endotoxin testing.

EndoSynX™ reconstructs the complete endotoxin detection cascade using recombinant Factor C, Factor B and Proclotting Enzyme, delivering robust sensitivity and reliable endotoxin detection without relying on horseshoe crab lysate.

Cat No.

1501114

Quantity

**96 Reactions
(2 Assays)**



USP-Equivalent Control Standard Endotoxin (CSE) Provided in the Kit

The CSE supplied with the kit is qualified against the USP Reference Standard Endotoxin (RSE), ensuring USP-traceable calibration, reliable assay performance, and lot-to-lot consistency.

- Homogeneity Verification: Representative vials from each CSE lot are tested in duplicate to demonstrate uniformity and consistency across the batch.
- Accuracy Verification: Assigned endotoxin potency is confirmed through back-calculation using serial dilutions of the USP RSE, including evaluation at concentrations as low as 0.05 EU/mL.

Reduce Cost Per Test -- One kit, Two independent Assays

Designed for maximum flexibility, a single kit supports two independent assay runs, allowing laboratories to maximize reagent utilization, minimize waste, and reduce testing costs.

rCKA Kit Components

Reagent	Part No.	Quantity	Storage
Recombinant Cascade Reagent A	PNR018	4 vials	2-8 °C
Recombinant Cascade Reagent B	PNR019	4 vials	
Recombinant Cascade Buffer	PNR016	2 × 2.5 mL	
Control Standard of Endotoxin	PNB028	2 vials	
96-well Microplate	/	2 plates	
Water for BET	NND072	4 × 8 mL	

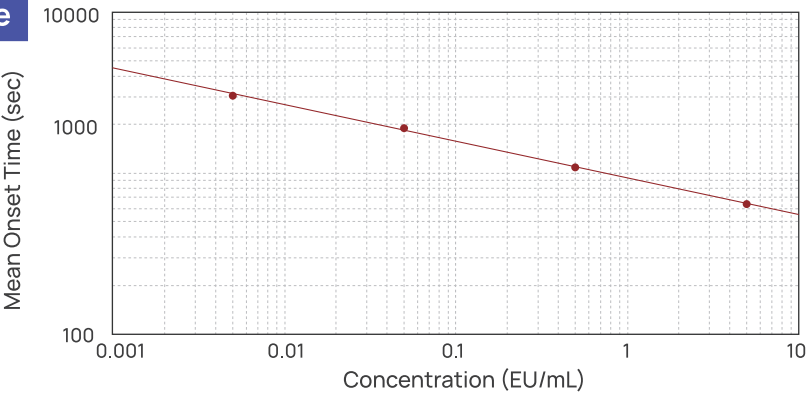
Wide Dynamic Range -- Ideal for routine QC laboratories

Delivering accurate and reliable endotoxin quantification over a broad dynamic range of 5–0.005 EU/mL, the kit ensures consistent performance from routine QC testing to ultra-low endotoxin analysis.

Calibration Curve Results at 5-0.005 EU/mL

Theoretical concentration (EU/mL)	Mean value detection (EU/mL)	Upper limit of 95% confidence interval of RSD	Upper limit of 95% confidence interval of recovery (%)	Lower limit of 95% confidence interval of recovery (%)
5	5.087	2.466	100.473	102.993
0.5	0.526	7.130	101.524	109.065
0.05	0.044	10.160	84.143	93.192
0.005	0.005	7.049	104.091	111.731

Standard Curve



● STD (Standards@20250520: Mean Time vs Concentration) Weighting: Fixed

Curve Fit: Log-Log

$Log(y) = A + B * Log(x)$

Curve Fit Results▲

	Parameter	Estimated Value	Std.Emor	Confidence Interval
STD R ² =0.999	A	2.965	0.006	[2.941, 2.989]
	B	-0.228	0.004	[-0.246, -0.211]



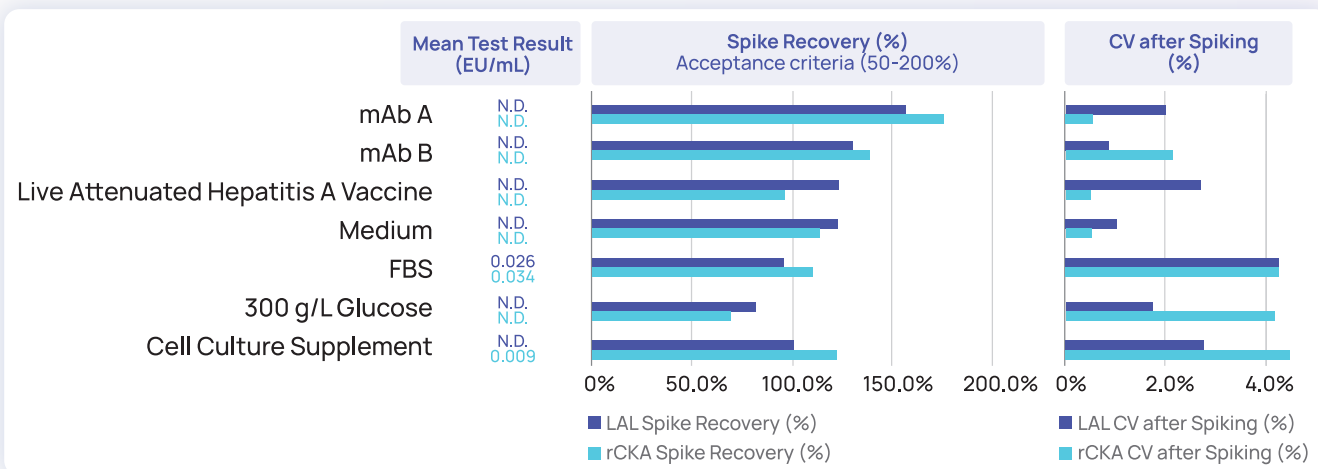
Assay Performance

Parameters	Acceptance Criteria
Linearity	5.0-0.005 EU/mL with correlation coefficient $ r \geq 0.999$
LOQ	0.005 EU/mL
Precision	Upper limit of 95% confidence interval of RSD for all the samples $\leq 30\%$
Accuracy	The 95% confidence interval of recovery within 95% -115%
Robustness	Consistent results across different microplates at 406 nm absorbance
Specificity	Demonstrated detection capability for endotoxins from various bacterial sources



Comparability in Endotoxin Detection: rCKA test vs. LAL test

Performance verification demonstrated that the EndoSynX™ rCKA Kit achieved recovery and repeatability comparable with the conventional LAL assay across a wide range of sample matrices.



Superior Anti-Interference Capability: rCKA test vs. rFC test

The EndoSynX™ rCKA Kit demonstrates superior resistance to sample matrix interference, achieving endotoxin detection performance comparable to the rFC assay even in minimally diluted samples.

Samples	MVD ($\lambda=0.005\text{EU/mL}$)	Non-Interfering Dilution (NID) Ratio		Spike Recovery (%) Acceptance criteria (50-200%)	
		rCKA	rFC	rCKA	rFC
Cell Culture Supernatant (with Phenol Red)	200	1	200	95.4	126.8
mAb A (High Protein)	200	1	2	175.4	135.4
Saline for Injection (High Salt)	50	2	16	89.6	116.8
Cell Culture Supplement (Pink)	100	2	16	122.6	79.0
Emulsifier (Milky White)	1000	40	640	110.4	151.8

Regulatory Compliance

Global regulatory authorities recognize scientifically justified recombinant endotoxin testing, including USP <86>, FDA Bacterial Endotoxins Test (BET) Guidance, and the European Pharmacopoeia.

Sustainability & ESG

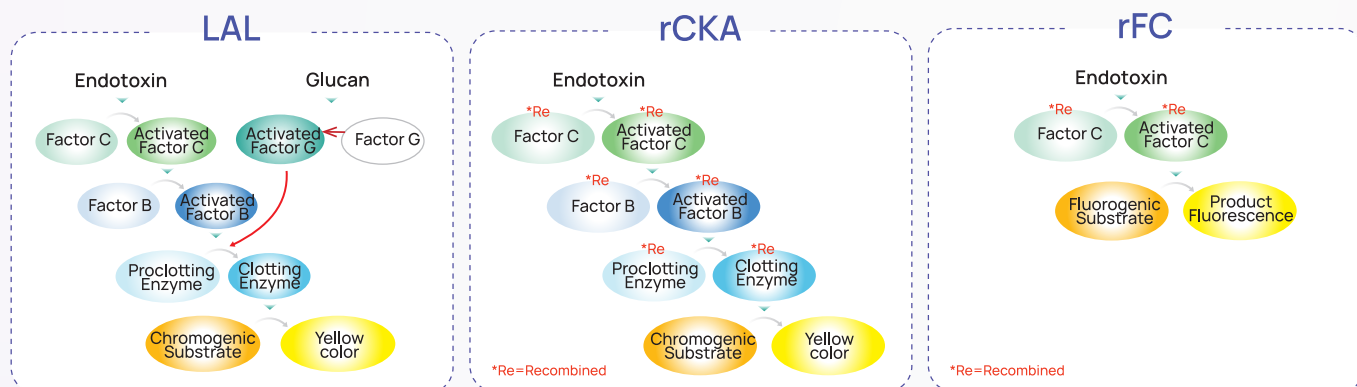
Recombinant reagents replace animal-derived reagents, supporting the 3Rs principles (Replace, Reduce, and Refine) and helping organizations achieve their ESG and sustainability goals.

Reliability & Consistency

Recombinant technology minimizes biological variability and delivers superior lot-to-lot consistency and better confidence in routine quality control.

A Smarter Approach to Endotoxin Testing - rCKA vs LAL and rFC Technologies

rCKA eliminates Factor G-mediated β -glucan interference, improving endotoxin specificity and reducing false-positive results. Unlike rFC, which relies solely on recombinant Factor C, rCKA reconstructs the complete recombinant horseshoe crab coagulation cascade, preserving the cascade amplification mechanism of conventional LAL in a fully animal-free format.



Ready to Move Beyond LAL?

EndoSynX™ empowers biopharmaceutical manufacturers' bacterial endotoxin testing workflow with confidence—combining scientific excellence, regulatory alignment, and sustainable innovation in one complete recombinant solution.



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