

















WASTE REDUCTION IN ENDOTOXIN TESTING PLATFORMS

From traditional to alternate endotoxin testing methods used for product release testing, there is an opportunity to **waste less** reagent and generate **cost savings**.



Waste in Endotoxin Detection Assays: LAL vs rFC

Given that Limulus Amoebocyte Lysate (LAL) is packaged in vials (2.6 or 5.2mL) and reconstituted as needed, there is inevitable waste compared to using recombinant Factor C (rFC). rFC is a liquid reagent that is prepared (combined as enzyme, buffer, and substrate) in a ratio that can be prepared in amounts very close to what is needed (no waste).

	ENDOZYME II GO assay and GOPLATE™ with rFC	ENDOZYME II GO STRIPS with rFC	LAL Cartridges	Traditional LAL
Method	rFC with 96-well microplate pre-filled CSE with required standard curve and positive product control concentrations (PPC). Up to 21 samples per assay.	rFC with 96-well STRIP-based microplate CSE pre-filled with required standard curve and positive product control concentrations (PPC). Up to 21 assays per hour.	Multi-cartridge system uses LAL-cartridge technology to run one sample per cartridge. LAL reagent, chromogenic substrate, and CSE are contained within disposable cartridges. One sample per assay and up to 5 parallel assays.	Traditional LAL assays with 96-well microplates. Standards and samples must be prepared. Involves high-volume pipetting. 21 samples per assay.
Technology	Plate based	STRIPS	Cartridge based	Plate based
Horseshoe Crab Blood				
Turnaround Time (per 21 tests*)				
Overall Waste**	0%	0%	0%	25-35%
Cost Savings** Based on Waste	25%	25%	N/A	0%
Environmental Impact				
Supply Chain Security				

*Marius M, et al. Comparison of Limulus Amoebocyte Lysate and Recombinant Factor C Assays for Endotoxin Detection in Four Human Vaccines with Complex Matrices. DOI: 10.5731/pdaipst.2019.010389. Epub 2020 Mar 16.

**Overall Waste/Cost Savings: Based on reagent use achieved using reconstituted vials (for LAL) versus preparation of volumes needed using liquid rFC reagents.