A Comparative Analysis of Absorbance-Based Endotoxin Testing Using Different Microplate Readers

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Purpose

- With Lonza's planned discontinuation of sales of the ELx808™ Microplate Reader, commonly used for endotoxin testing, it is imperative for QC laboratories to find, evaluate, and implement a new reader for their normal operations. The aim of this study is to compare the performance of ELx808™ and Nebula® Absorbance Reader for their ability to measure absorbance-based endotoxin levels accurately and reliably
- Key Performance Indicators used for this study: accuracy, variability, and reaction time
- The results may be particularly useful for laboratories seeking to replace their current microplate readers or for those interested in optimizing their endotoxin testing protocols

The Nebula® Absorbance Reader

- 96-well microplate reader
- **Read capabilities:** Absorbance (monochromator)
- **Light source:** Xenon Flash
- **Detection:** Silicon photodiode
- **Wavelength range:** 230 – 1000nm
- Optimized to work with WinKQCL® Endotoxin Detection and Analysis Software and traditional LAL assays such as the PYROGENT® 5000 Kinetic Turbidimetric Assay and the Kinetic-QCL® Kinetic Chromogenic Assay

Results

Sample predictions

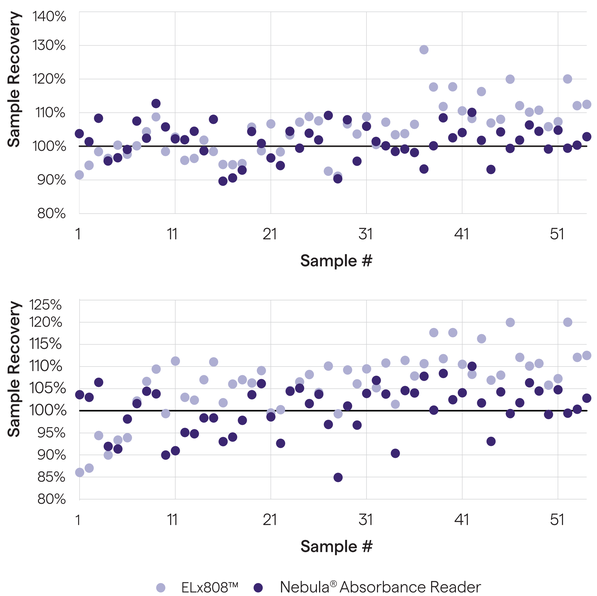
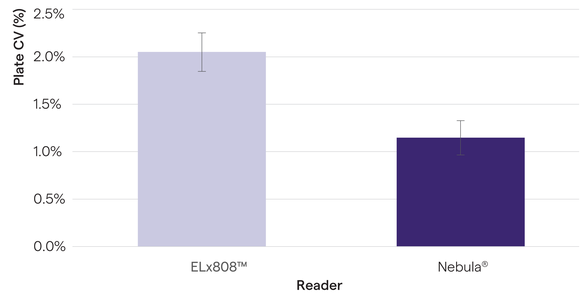


Figure 1. 54 samples for each chemistry, 18 at each concentration (0.025, 0.25, and 2.5 EU/mL for KQCL, 0.05, 0.5, and 5 EU/mL for Pyrogent® 5000)

	KQCL Sample Predictions		Pyrogent® 5000 Sample Predictions	
	Average	CV	Average	CV
ELx808™	105%	8.0%	106%	7.4%
Nebula® Absorbance Reader	101%	5.2%	100%	5.5%

Uniformities

Kinetic-QCL® 0.5 EU/mL Uniformity Plate CVs



Pyrogent® 5000 1 EU/mL Unifirmity Plate CVs

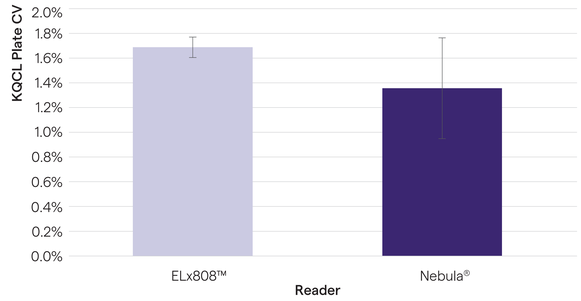
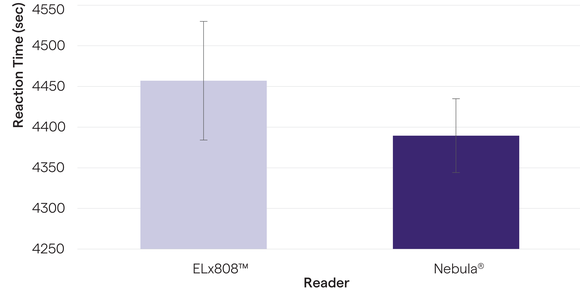


Figure 2. Uniformity testing

Reaction Time

Kinetic-QCL® 0.005 EU/mL Reactions Times



Pyrogent® 5000 0.01 EU/mL Reactions Times

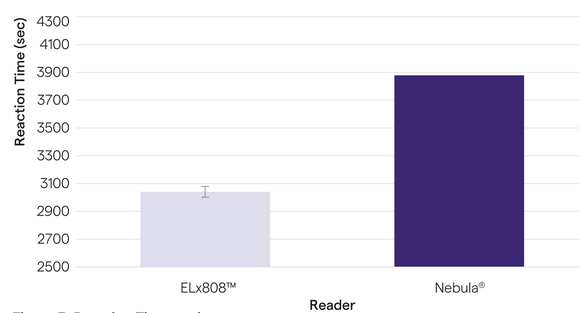


Figure 3. Reaction Time testing

Conclusion

- The data provided supports that the Nebula® Absorbance Reader is a suitable replacement for ELx808™ and it is fit for use for all of Lonza's quantitative endotoxin detection absorbance assays
- Nebula® Absorbance Reader demonstrated comparable performance to ELx808™ with slight improvements in sample prediction accuracy and consistency
- When using PYROGENT® 5000 Kinetic Turbidimetric Assay, the Nebula® Absorbance Reader demonstrated slower reaction times for the low standard (0.01 EU/mL)

All charts and figures were created using data from the Lonza's 2023 Nebula Validation Study.

RT-P0029 08/23