Enabling a Healthier World

Lonza

Competitive Landscape

Microplate Readers

Nebula® Distributor Training I January 2024

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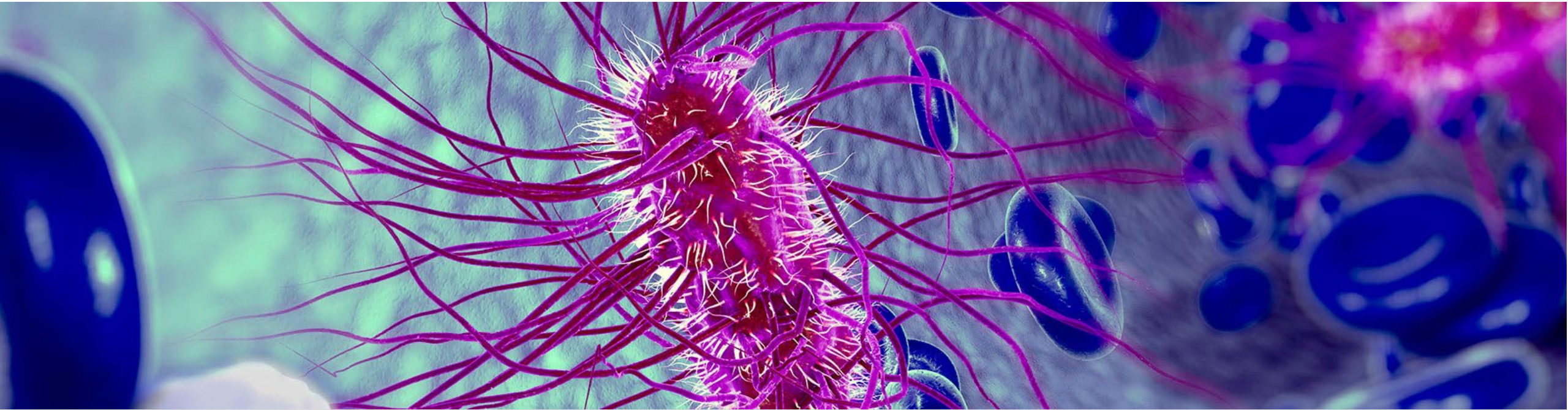

Nebula® Microplate Readers

Overview

- The Nebula® Microplate Reader is part of Lonza's comprehensive range of testing solutions supporting your efforts in pyrogen and endotoxin testing of raw materials, in-process samples and manufactured product

- The Lonza Nebula® Reader is designed for use in the QC lab for endotoxin testing and it provides high performance for most of today's microplate applications and research

Nebula® Microplate Readers

Overview

- 96-well microplate reader
- Monochromator-based wavelength selection
- High performance optics
- Tray Insert to better distribute the heat across the microplate and increase robustness in absorbance assays
- Optimized to work with WinKQCL® Endotoxin Detection and Analysis Software and our traditional LAL assays and recombinant Factor C technology
- Two versions:
  - Multimode (absorbance and fluorescence capabilities, pn 25-375S)
  - Absorbance (pn 25-365S)

Nebula® Microplate Readers

Overview

- **Absorbance** unit works with WinKQCL® Endotoxin Detection and Analysis Software and our traditional LAL assays such as the PYROGENT® 5000 Kinetic Turbidimetric Assay and the Kinetic-QCL® Kinetic Chromogenic Assay

- **Multimode** unit works with WinKQCL® Endotoxin Detection and Analysis Software, PYROGENT® 5000 Kinetic Turbidimetric Assay, the Kinetic-QCL® Kinetic Chromogenic Assay, **and** the PyroGene® rFC Assay

Nebula® Multimode Reader

Benefits

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One Reader. Two Detection Methods.

Features	Advantages	Benefits
Absorbance and fluorescence detection capability	Can run traditional and rFC assays	Reduce risk
Smaller than two readers	Takes up less lab space	More free lab space
Monochromator-based	Ease of use	Saves money
Reduced maintenance	½ Yearly maintenance costs	Saves time
Streamlined training	Less time to train analysts	

Nebula® Multimode Reader

Positioning/customer profile

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Small Customers

- QC laboratories
- Method validation/R&D Teams
- Interested In rFC
- Reduced risk (LAL and rFC)
- Limited lab space

Medium Customers

- QC laboratories
- Method validation/R&D Teams
- Interested In rFC
- Reduced risk (LAL and rFC)
- Limited lab space

Large Customers

- Method validation/R&D Teams
- Interested In rFC
- Reduced risk (LAL and rFC)
- Limited lab space

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Nebula® Multimode Reader

Summary

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Product Overview

- 25-375S
- Nebula® Multimode Reader
- Dimensions: 42.5 cm W x 45.7 cm D x 25.3 cm H (16.73" W x 17.99" D x 9.96" H)
- Weight: 15.8 kg (34.8 lbs.)

Key Features

- Read capabilities: absorbance (PYROGENT® 5000, Kinetic-QCL®) and fluorescence (PyroGene® rFC)
- Optimized to work with WinKQCL® Endotoxin Detection and Analysis Software
- Supports readout of MAT/ ELISA
- Tray insert to better distribute the heat across the microplate and increase robustness in absorbance assays

Why Do We Win?

- Strength of our portfolio. We offer a complete pyrogen and endotoxin testing solution to help you efficiently test your raw materials and manufactured products today and in the future
- Space! There is limited space in the bench, having 2 readers in one is huge!
- rFC. The push towards sustainability and minimizing reliability towards animal resources is only going to get bigger
- Software – no need to learn a new platform. All readers work with WinKQCL® Software

Objection Handling

- Isn't this the same as Tecan's Infinite® M unit?
  - A: No. We have updated the unit's firmware so we can optimize it to work with WinKQCL® Software
- I am not looking into rFC right now
  - A: Worldwide, there is a growing appeal in the pharmaceutical industry for recombinant technologies. Recently the European Pharmacopoeia Commission recently adopted revised versions of various texts, including two monographs on pharmaceutical waters to add the possibility of performing the control of bacterial endotoxins using rFC

Nebula® Absorbance Reader

Benefits

Lonza

Accuracy and precision that will boost your efficiency.

Features	Advantages	Benefits
Optimized excitation monochromator	Can run PYROGENT® 5000 and Kinetic-QCL® Assays	Reduce risk of false negative or false positives in testing
High-performance optics	Precise measurements of endotoxin levels	Faster decision-making
Streamlined training	Integration with WinKQCL® Software	Saves time

Nebula® Absorbance Reader

Positioning/customer profile

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Small Customers

- QC laboratories
- Method validation/R&D Teams
- Existing ELx808 users

Medium Customers

- QC laboratories
- Method validation/R&D Teams
- Existing ELx808 users

Large Customers

- Method validation/R&D Teams
- Existing ELx808 users

If they are heavy chrome users, the Absorbance version is your best chance. You should target ELx808 users with no interest in rFC

Nebula® Microplate Readers

At a glance

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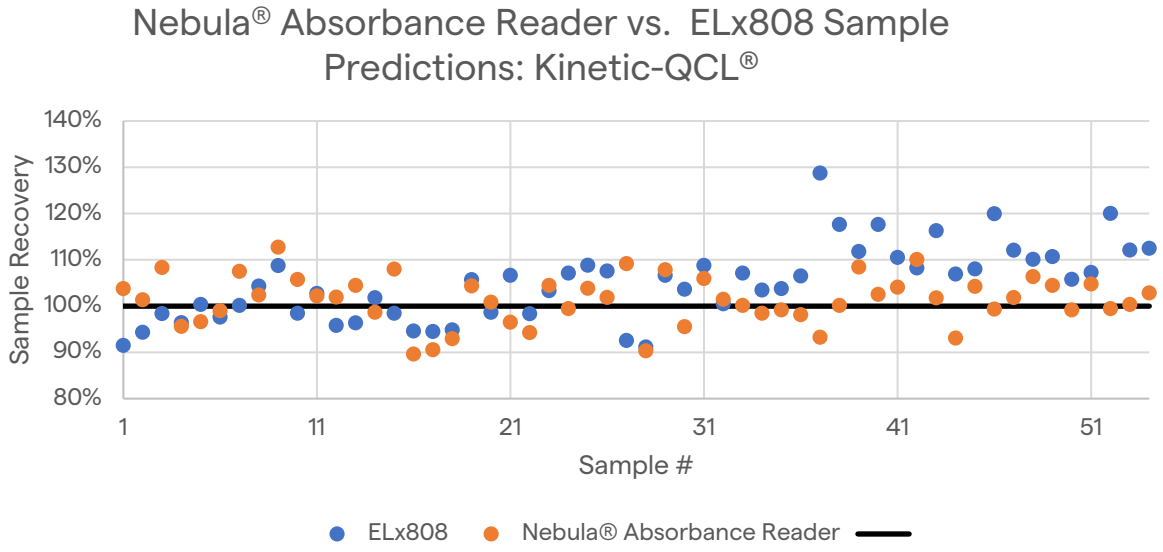
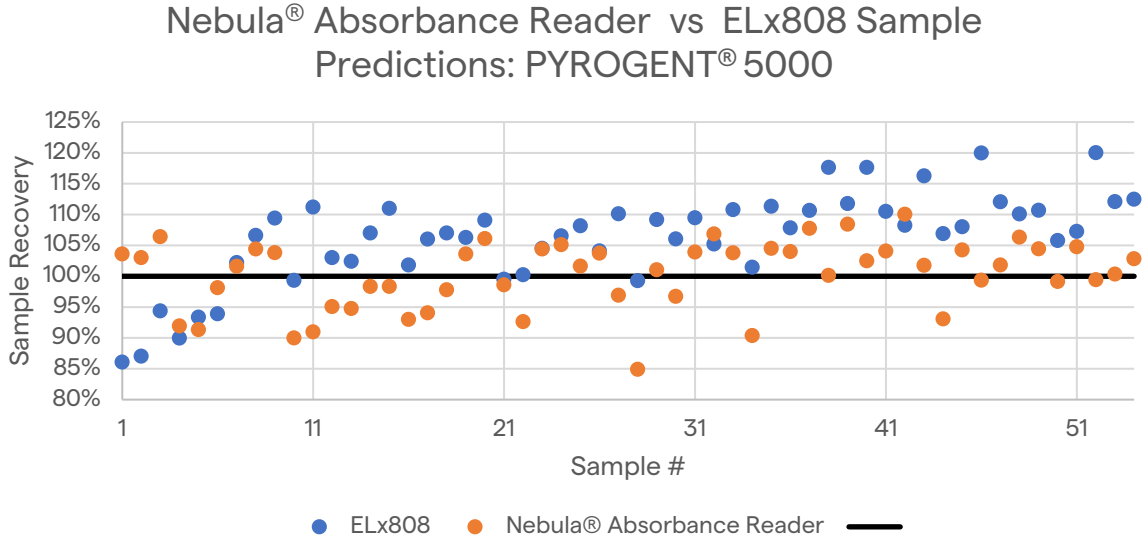
	Nebula® Multimode	Nebula® Absorbance
General		
Plate Type	96-well plates	96-well plates
Measurement	Software controlled	Software controlled
Interface	USB	USB
Filter Handling	Monochromator-based wavelength selection – no filters necessary	Monochromator-based wavelength selection – no filters necessary
Plate Definition	Via scanning software	Via scanning software
Temperature Control	From 5 °C above ambient up to 42 °C	From 5 °C above ambient up to 42 °C
Plate Shaking	Linear and orbital shaking, amplitude selectable from 1 – 6 mm in 0.5 mm steps	Linear and orbital shaking, amplitude selectable from 1 – 6 mm in 0.5 mm steps
Light Source	High energy xenon flash lamp, lifetime: 10^8 flashes	High energy xenon flash lamp, lifetime: 10^8 flashes
Optics	Fused Silica Lenses	Fused Silica Lenses
Detectors		
Fluorescence	Spectrally enhanced PMT: red-sensitive PMT	n/a
Absorbance	Silicon photodiode	Silicon photodiode
Power Supply	Auto-sensing: 100 – 120 V/220 – 240 V, 50-60 Hz	Auto-sensing: 100 – 120 V/220 – 240 V, 50-60 Hz
Outer Dimensions		
Basic instrument	Width: 425 mm / 16.73 inches	Width: 425 mm / 16.73 inches
	Height: 253 mm / 9.96 inches	Height: 253 mm / 9.96 inches
	Depth: 457 mm / 17.99 inches	Depth: 457 mm / 17.99 inches
Weight	15.8 kg	15.8 kg
Ambient Temperature		
Operation	+ 15 °C to + 30 °C / (+ 59 °F to + 86 °F)	+ 15 °C to + 30 °C / (+ 59 °F to + 86 °F)
Non-operation	- 20 °C to + 60 °C / (- 4 °F to + 140 °F)	- 20 °C to + 60 °C / (- 4 °F to + 140 °F)
Relative Humidity		
Operation	< 80 % non condensing	< 80 % non condensing
Over-voltage Category	II	II
Usage	General Laboratory Instrument	General Laboratory Instrument
Noise Level	< 60 dBA	< 60 dBA
Pollution Degree	2	2
Method of Disposal	Electronic waste (infectious waste)	Electronic waste (infectious waste)

Nebula® Absorbance Reader

ELx808 comparison





Conclusion

- The data supports that Nebula® Absorbance Reader is a suitable replacement for ELx808 and it is fit for use for all Lonza's quantitative endotoxin detection absorbance assays
- Nebula® Absorbance Reader demonstrated comparable performance to ELx808 with slight improvements in sample prediction accuracy and consistency

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Nebula® Absorbance Reader

Summary

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- Tray Insert to better distribute the heat across the microplate and increase robustness in absorbance assays

Why Do We Win?

- Strength of our portfolio. We offer a complete pyrogen and endotoxin testing solution to help you test your raw materials and manufactured products today and in the future
- Our data showcases as the Nebula® Reader as the best option for our assays in the market
- Software – no need to learn a new platform. All readers work with WinKQCL® Software

Objection Handling

- ELx808 is a workhorse / I don't need to replace my ELx808
  - A: BioTek stops selling ELx808 in November 2023. Now is the time to upgrade. Waiting until the ELx808 breaks might be too much of a downtime risk. We have the resources (service offering) to minimize downtime risk and keep business continuity during the transition and after implementation

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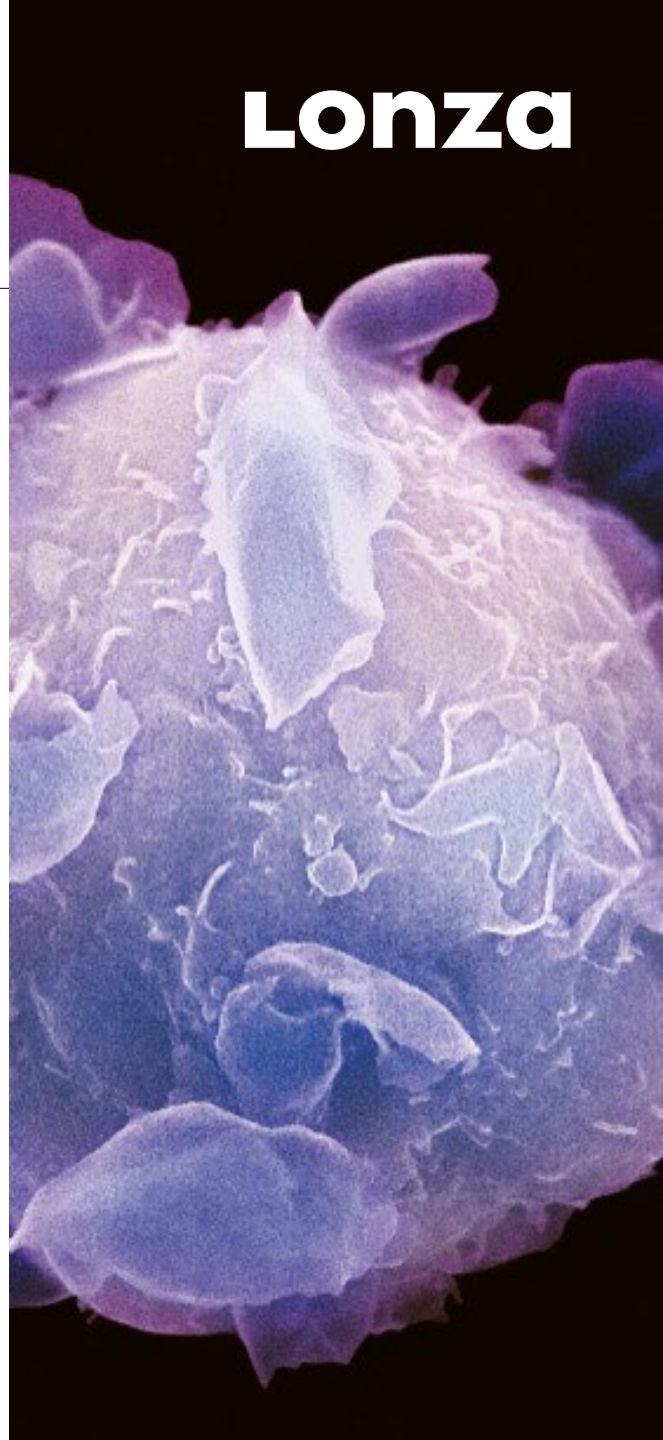
Nebula® Reader

Competitive landscape

- BioTek/ Agilent stops selling ELx808 in November 2023 | End of Service January 2029
- CR has replaced ELx808 Microplate reader with what appears to be a custom version of Agilent's Epoch 2, branded as **Endosafe® PRS 3**
- ACC has not announced an ELx808 replacement yet
- Our exhaustive R&D process determined Tecan's Infinite® M to be the best solution available in the market for our chromogenic and turbidimetric assays. Nebula® Absorbance Reader will offer comparable performance to the ELx808 unit
  - We have updated Tecan's Infinite ® M firmware to work with WinKQCL® Software and unlock its full potential
  - We have added a tray insert, only available with a Nebula® Reader, to better distribute the heat across the microplate and increase robustness in our assays



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Endosafe® PRS 3

- Absorbance-based monochromator 96-well microplate reader based on Agilent's Epoch 2
- Compatible with Kinetic Turbidimetric LAL (KTA), Kinetic Turbidimetric LAL (KTA2), Kinetic Chromogenic LAL (KCA), and Recombinant Cascade Reagent rCR (Trillium®)
- Compatible with EndoScan-V™ Software version 6.2 and above
- Cons:
  - Epoch 2 heats up plate slower than ELx808 and shows more variation across plate

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Sievers Eclipse platform

- Three components: an analyzer, microplate, and software
- Designed for quality control testing of water and drug product within the pharmaceutical, medical device, and hemodialysis markets
- Cons:
  - Software is not barcode ready and cannot import LIMS sample identifications
  - Time savings claim not applicable for complex samples (dilution or pre-treatment time considerations)
  - For those who have complex samples the time taken for sample prep manually makes the time saving for plating out insignificant

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Nebula® Microplate Readers

Comparison

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Features	ELx808	Endosafe® PRS3	Eclipse	Nebula® Multimode
Light Source	Halogen Bulb	Xenon flash lamp	LED emitter	Xenon flash lamp
Detection Mode	Absorbance	Absorbance	Absorbance	Absorbance, Fluorescence
Wavelength Selection	Filters	Monochromator		Monochromator
Wavelength Range	340-900 nm	200-999 nm	405 nm Optical Wavelength Filter	230 – 1000 nm (Absorbance), 230 – 850nm (Fluorescence)
Loading Method	Top-load	Front-load	Top-load	Front-load
Weight	35 lbs.	25 lbs.	22.1 lbs.	34.8 lbs.
	(15.87 kg)	(11.34 kg)	(10 kg)	(15.8kg)
Dimensions	16.0" D x 15.5" W x 8.75" H	8.5″ H x 12.75″ W x 15.5″ D	6.9"H x 13.8"W x 19.8"D	16.73" W x 17.99" D x 9.96" H
	(40.6 cm x 39.37 cm x 22.2 cm)	(22 x 32.3 x 39.54 cm)	(17.5 cm x 35.1 cm x 50.3 cm)	(42.5 cm x 45.7 cm x 25.3 cm)
Power	24-volt external power supply compatible with 100-240 V~ ± 10% @ 50-60 Hz	External 24 VDC power supply compatible with 100–240 volts AC at 50–60 Hz. 60 W maximum consumption.	100–240 Volts AC @50/60 Hz	Auto-sensing: 100 – 120 V/220 – 240 V, 50 – 60 Hz
Ports	Serial/Parallel	1 USB Type-A	USB	USB
Reagents	Kinetic Turbidimetric LAL (KTA), Kinetic Turbidimetric LAL (KTA2), Kinetic Chromogenic LAL (KCA)	Kinetic Turbidimetric LAL (KTA), Kinetic Turbidimetric LAL (KTA2), Kinetic Chromogenic LAL (KCA), and Recombinant Cascade Reagent rCR (Trillium®).	Kinetic Chromogenic	Lonza's turbidimetric, chromogenic and fluorescence (rFC) assays
Accuracy	<1% at 2.5 OD typical <2% at 3.5 OD typical	<1% at 2 OD <3% at 2.5 OD	≤ 5% deviation from expected value	0-2 OD <± (1% + 10 mOD) 2-3 OD <± 2.5%

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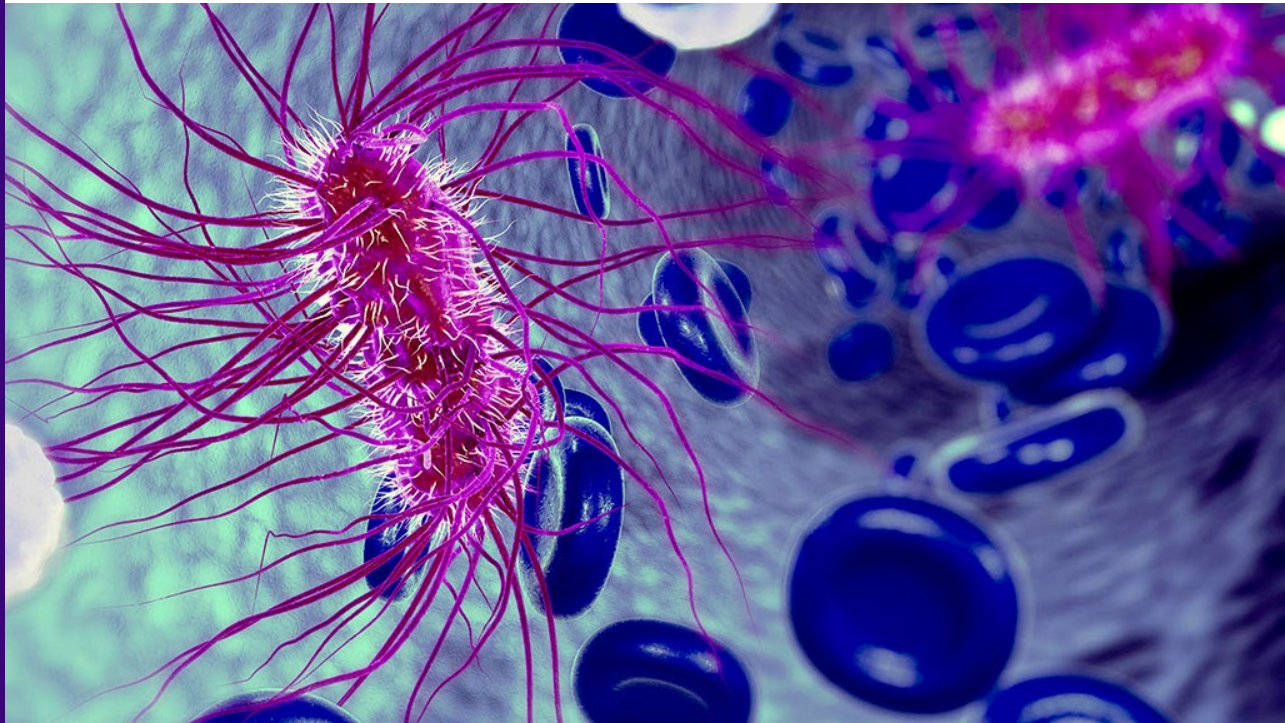
Questions?