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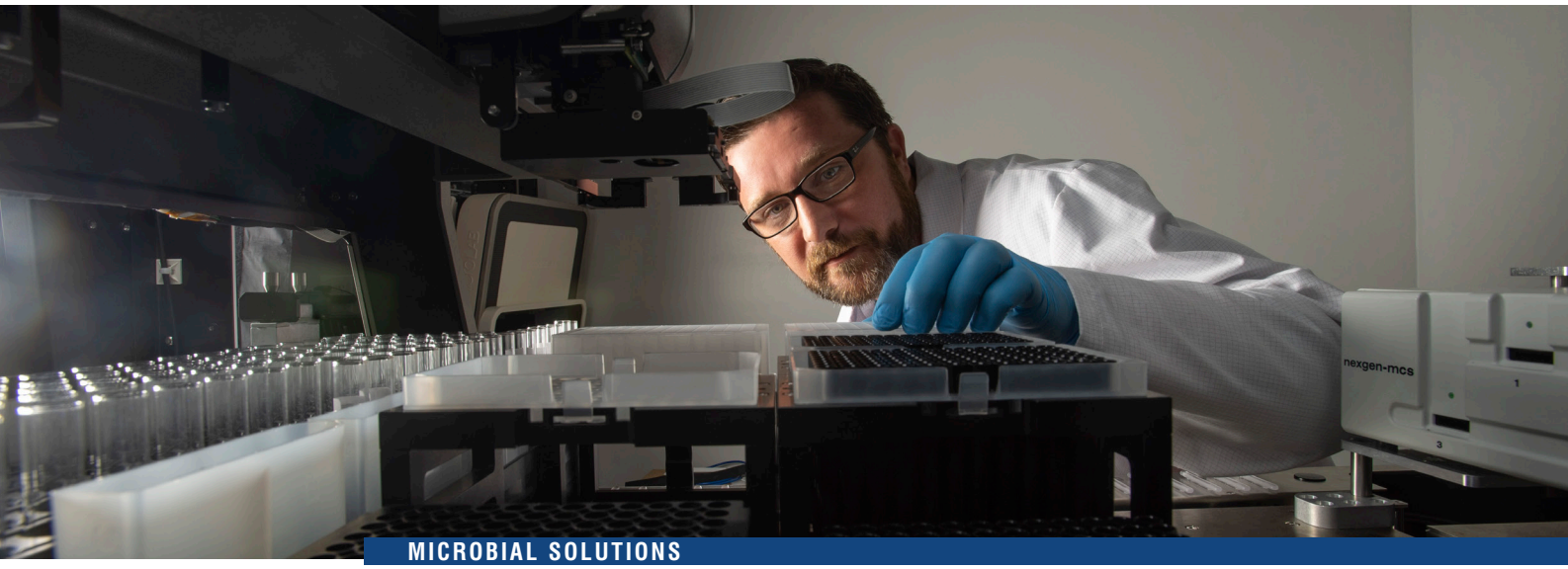

MICROBIAL SOLUTIONS

Endosafe® Nexus 200™: Automation Through Robotics for Bacterial Endotoxin Testing

Features and Benefits of the Endosafe Nexus 200

- Fully automated walkaway robotic testing system reduces human intervention and optimizes resources
- Fully enclosed platform with safety locking features
- Increased sample throughput capability, testing up to 120 diluted & undiluted samples per run
- Process complex and serial dilutions with multiple diluents, allowing for water, in-process, and final product testing
- Utilizes both Endosafe® LAL and Trillium™ recombinant cascade reagent (rCR) cartridges for simple, accurate, and quantitative testing
- Powered by Endosafe EndoScan-V™ software allowing for LIMS integration and improved traceability, security, and data management

Endotoxin testing has traditionally required extensive assay and standard curve preparation, sample preparation, reagent rehydration, and multiple dilutions to be made for a successful result. These tasks increase the inherent risk for human errors made during sample processing, leading to potential data integrity violations and gaps. As expectations continue to evolve within the pharmaceutical and biotech industry, microbiological quality control and production environments are setting the standard for implementing reliable, compliant, and cutting-edge testing methods and technologies.

With this paradigm shift of introducing automation in the lab, keeping up with product demand, regulatory compliance, and technological advances can seem like a never-ending task. However, developments in machine-driven instrumentation for automating endotoxin testing and data management are driving operational efficiencies, data integrity compliance, and ultimately eliminating hands-on testing to relieve analysts from repetitive and manual, although necessary, duties.

The advantages of implementing automation are no longer just for high-volume, large manufacturing organizations. Tangible benefits go beyond just an increase in production, and include mitigating your firm's risk for human error, optimizing subject matter experts resources, and harmonizing training, software, and systems across global sites.

Since the launch of the first fully automated robotic Endosafe® Nexus™ in 2014, transformations in technology and innovation have inspired our Research and Product Development team to reimagine the next iteration of automated endotoxin testing with the Endosafe Nexus 200™. The next generation of our data integrity compliant, walkaway automated robotic instrument can test up to 120 samples per run and perform complex and serial dilutions via Endosafe cartridge technology in a fully enclosed system.

Increase Productivity and Employee Efficiency

Performing endotoxin testing on large numbers of samples using traditional methods can be both time-consuming and vulnerable to outside influences such as technician errors and standard curve anomalies. Manual processes, or those with numerous manual steps, often lead to inefficiencies within the lab, which can lead to costs in terms of both time and money, as well as pose a risk to product quality. The training required for an analyst to become proficient in running these

assays can be considerable and adds to the overall cost and complexity of performing endotoxin testing. Having highly educated employees performing hours of serial dilution steps and creating standard curves is not an efficient use of their skills and can lead to increased rates of human error and staff turnover due to lack of satisfaction in their work. Additionally, the possibility always exists that an error may be discovered at the end of an assay, necessitating investigation and retesting.

By automating repetitive tasks, you free up your subject matter experts to perform higher-value work such as interpreting data, analyzing trends, and proactively addressing risks. That benefits your bottom line. Automation minimizes variation, time, and resources of performing both laboratory and out of specification investigations.

Integrating Endosafe Technology into One All-inclusive Package

The Nexus 200 is the perfect amalgam of technology, innovation, and control to optimize and streamline your QC testing lab by combining both the Endosafe LAL and Trillium recombinant cascade reagent (rCR) cartridges, the Endosafe® nexgen-MCS™ multi-cartridge system, and the Hamilton Microlab® Nimbus platforms for the ideal, low-maintenance, walkaway BET platform.

The cartridges are designed to optimize a bacterial endotoxin test. As the cartridges are pre-filled, they eliminate the manual daily preparation of standards and reagents. Consolidating all the essential components in a self-contained cartridge reduces pipetting steps, decreases assay variability, cross-contamination, false positive risk, and retest rates. The cartridges contain four reservoirs that represent duplicate sample and spike channels that allow the test to automatically run in duplicate as is the requirement for standard BET testing.

A Cartridge Stability study has been performed by Charles River to confirm that cartridges are stable over an extended period for use on longer automation runs. A customer-facing memo and SOP that customers can purchase to follow and perform their own stability study is available. Memos regarding the mixing protocol, consumables stability, data around reliability and robustness, and further testing data are available upon request.

The nexgen-MCS multi-cartridge benchtop system is proficient at concurrently testing up to five samples within 15 minutes for rapid, quantitative, and accurate endotoxin results. The system was designed to be compliant with global pharmacopoeia for LAL methods, meet the BET criteria for photometric techniques, and be consistent with the FDA's PAT initiative.

The Nexus 200 system architecture was built on the Hamilton Microlab NIMBUS HD platform, a compact liquid handling system, offering speed, ease of use and superior pipetting performance. The small footprint, proven and precise air displacement pipetting, and ease of maintenance make it ideal for endotoxin testing via cartridge technology.

System Operation

1. Analyst loads required cartridges, consumables, and samples on deck.
2. Barcode on sample tube is scanned for sample information and confirmed by analyst.
3. Door locks, then robotic gripper adds cartridge to nexgen-MCS slot.
4. Pipetting arm prepares sample and adds to cartridge wells, then prompts nexgen-MCS to begin assay.
5. When assay is complete, gripper takes cartridge out of nexgen-MCS and discards into bin.
6. Steps 3 and 4 are repeated until all samples are tested.
7. Analyst reviews test results using EndoScan-V integrated software and can print or send to LIMS for further analysis.

Service and Validation Programs

From regular maintenance and annual calibration to on-demand service contracts, our dedicated Client Implementation Team is the single point of contact for all your service requirements, providing superior, timely service delivery and a simple, streamlined process for obtaining support. Choose from the plans below or contact our team for a program tailored to your needs.

Additionally, we offer validation services to assist customers to speed up bringing their automation online. We can offer this service remotely for customers who want to send their samples into one of our global labs or can offer the service on-site as an additional week of training at the initial install of the Nexus system.

Endosafe® Nexus™ & Nexus 200™ Feature Comparison Chart

Feature	Endosafe® Nexus™	Endosafe® Nexus 200™
Sample capacity per automation session	Up to 60 samples	Up to 120 diluted or undiluted samples
Dilution ratios	Single dilution up to 1:300	Multiple dilutions up to 1:32,768
Number of Pipette Heads	1	4 (increases speed of sample handling)
Number of Pipette Tips	96 per tip style	Over 700 total tips
Sample rack	2 x 24 or 2 x 32 position racks	6 x 20 sample tube racks
Bar Code	1D barcode	1D and 2D barcode options
Operating system compatibility	Windows 10 and 11	Windows 10 and 11
Controller	External PC	External PC
Application	Integrated Nexus 2.7 software	EndoScan-V™ version 6.2 and above
Hardware Configuration	Single benchtop configuration with baskets for waste	Closed unit with integrated cabinet, waste chute
Data Integrity features	Validated software with audit trails	• Validated software with searchable audit trails • PC controls power to all hardware • Limited human interaction to eliminate variability • Fully flexible user management • Includes digital signature
Safety	Third party enclosure available for purchase	• Completely enclosed • Doors locked to start automation and will not unlock unless robot is parked. • Locking caster wheels on cabinet
Dimensions	50"L X 21"W X 32"H (127 X 54 X 82 cm)	Maximum Working Width of System: *System with Cabinet, **Optional Monitor Arm** and Door Open (not including user's computer)* 30"D X 96"W X 86"H (76.2 x 240 x 218.4 cm) *System with Cabinet, **Optional Monitor Arm** and Door Closed (not including user's computer)* 30"D X 96"W X 69"H (76.2 x 240 x 175.3 cm) *System with Cabinet and Door Open* 30"D X 60"W X 86"H (76.2 x 152.4 x 218.4 cm) *System with Cabinet and Door Closed* 30"D X 60"W X 69"H (76.2 x 152.4 x 175.3 cm) *System Boxed in Crate* 69.25"L X 34.25"W X 87"H (176 x 87 x 221 cm)
Weight	335 lbs (152 kg)	*Shipping Crate with Cabinet* 1000 lbs (453 kgs) *System* 615 lbs (279 kgs)

Endosafe® Nexus 200™ Ordering Information

Product Line	Product	Code
Endosafe® Nexus 200™	**Nexus 200™ Robotic System** Next generation Nexus™ platform nexgen-MCS™ instrument 3 cartridge dispensers 6 20-position racks Endoscan-V™ software Cabinet	MR750020K
Endosafe® Nexus 200™ Accessories	**20-Position Labware Rack**	MR7500R20
	Cartridge Dispenser	MR7500CD
	Monitor Mount Arm	MR884
Endosafe® Nexus 200™ Consumables*	**Conductive CO-RE® II 300 µL Tips, Nested** (pack of 1,920)	MR300N
	Reagent Containers (28 per case)	MR850
	Deep Well Plates (32 per case)	MR860
	Conductive CO-RE® II 1000 µL Tips (3,840 per case)	MR1001
	13 mm × 100 mm Borosilicate Glass Tubes, in Foil (pack of 50)	T300
Endosafe® Nexus 200™ Service and Support	**Annual Maintenance and Qualification Service**	MR2900
	Full Service Contract Including Annual Qualification	MR2900FS
	Installation Including IQ/OQ/PQ Service	MR2902
	IQ/OQ/PQ Service Kit	MR2902K
	On-Demand Repair Services: Labor only (hourly rate)	MR2903
	Standard Service Contract Including Annual Qualification	MR2905
	Software Validation Package	MR2600

*Consumables have been validated specifically for use with the Nexus 200™ Robotic System.

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