



MICROBIAL SOLUTIONS

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Operational Benefits and Features

- High-throughput capability, testing 48-60 samples per run
- Automated dilution and sample handling with the ability to suspend current run
- Small footprint: 30" H x 20" W x 54" L (76 x 51 x 137 cm)
- Utilizes FDA-licensed PTS™ cartridges
- Enhanced data management with barcoding technology
- Results obtained via Nexus™ integrated software
- Ideal for central lab water and product testing

[Interested in finding out more about Endosafe® Nexus™?](#)

Endosafe® Nexus™

How many investigations have you completed and the root cause was deemed human error?

The **Endosafe® Nexus™** is the first completely automated robotic system designed specifically for endotoxin testing in the central QC lab, unlocking the full potential of our unique [cartridge technology](#). Endotoxin testing has traditionally required extensive assay preparation, reagent rehydration, standard curve preparation, 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. The Nexus™ is a fully automated endotoxin testing system that combines consistent results with timely data, and that reduces variability and the need for subsequent investigations (see Figures 3 and 4). The Nexus™ utilizes innovative LAL cartridge technology, a state-of-the-art liquid handling system, and simple data management software to test 48 to 60 samples with minimal preparation and supervision.

The Endosafe® Nexus™ eliminates the complications, lost time, and potential for error associated with traditional high-volume endotoxin testing. With minimal training and involvement required to run the assay, technicians simply load the deck, confirm the sample bar codes have been read correctly, and walk away while the Nexus™ does the rest.

What if you could greatly reduce your current retest rate?

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. The time required to prepare standards and samples can often exceed the assay time while simultaneously tying up valuable resources, namely the analysts involved. The training required for an analyst to become proficient in running these assays is also considerable and adds to the overall cost and complexity of performing endotoxin testing. Additionally, the possibility always exists that an error may be discovered at the end of an assay, necessitating investigation and retesting.

EVERY STEP OF THE WAY

Primary Components

Endosafe® LAL cartridge technology

The disposable [Endosafe® cartridges](#) contain precise amounts of LAL reagent, chromogenic substrate, and control standard endotoxin (CSE). They are manufactured in accordance with rigid QC procedures and have been approved by the FDA for in-process and final product release testing. The disposable cartridge contains four channels: two channels with CSE and LAL, which serve as the positive control channels, and two channels with LAL for testing of samples. To perform the test, add 25 μ L of sample (at a non-interfering dilution) into all four sample reservoirs. The reader's internal pump moves the sample along the channels' reagent stations for mixing, then into the optical cells of the cartridge to be read kinetically.

Endosafe® nexgen-MCS™ multi-cartridge system

The [nexgen-MCS™](#) uses LAL kinetic chromogenic methodology that measures color intensity directly related to the endotoxin concentration in a sample. This multi-cartridge system was designed to be compliant with global pharmacopoeia methods, meet the BET criteria for photometric techniques, and be consistent with the FDA's PAT initiative.

Nexus™ integrated software

The software is consistent with FDA requirements and performs requisite calculations and batch reports for product release. For added protection, it generates secure data files and audit trails on all actions involving test data. The program was designed with flexible configuration capabilities and networking and performance options to facilitate gains in operational nexgen-MCS™ efficiency. The Nexus™ software features a searchable audit trail, which enables a reconstruction of all events if necessary. Audit trail searches can be printed and manually signed. The ability to reconstruct critical elements of data generation gives firms more insight into the investigative process during unexpected events and ultimately ensures compliance with data integrity standards.

Hamilton Microlab® NIMBUS

The Microlab® NIMBUS is a compact, automated liquid handler, offering speed, flexibility, ease of use, and superior pipetting performance. The small footprint, proven and precise air displacement pipetting, and flexible deck layout make it ideal for central lab endotoxin testing.

Product Features

Air displacement pipetting

The Nexus™ utilizes an air displacement pipetting process (Figure 1) instead of traditional water-based pipetting, as this reduces risk of contamination or sample dilution. A plunger/piston drives air downward, creating a vacuum. As the plunger moves upward, the sample is aspirated into the tip, while maintaining an air buffer. When the plunger moves back downward, the sample is dispensed, creating high pipetting accuracy and precision from sub- μ L to large (> 1 mL) volumes. With no system liquids, diluters, valves, or complicated tubing, no maintenance by the user is required.

Compressed O-ring expansion tip attachment (CO-RE technology)

CO-RE technology attaches disposable pipetting tips using a highly robust lock-and-key-style mechanism (Figure 2). This enables a positional precision of +0.1 mm on all axes. The system requires virtually no vertical force for tip attachment or ejection, thus eliminating mechanical stress and minimizing cross-contamination caused by the production of aerosols. Reduced stress also improves overall system reliability and throughput.

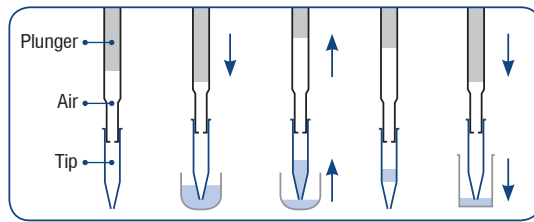


Figure 1. The Nexus™ utilizes an air displacement pipetting process instead of traditional water-based pipetting. A plunger/piston drives air downward, creating a vacuum. As the plunger moves upward, the sample is aspirated into the tip, while maintaining an air buffer. When the plunger moves back downward, the sample is dispensed.

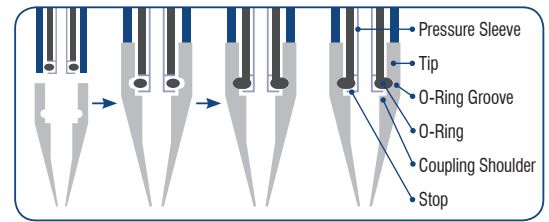


Figure 2. In the CO-RE technology, O-rings expand into grooves within the tip to secure it in place. Contracting the O-rings allows the tip to be ejected. This creates less stress on the system and improves performance.

Shift-and-scan barcode

Eliminating the need to manually enter sample information, the universal 1D barcode scanner provides a positive sample ID prior to inventory of samples. The current configuration contains two sample racks per deck with either 12 mm-13 mm tubes (total of 60 samples on deck) or 15 mL Falcon tubes (total of 48 samples on deck), with the ability to use different tube types in separate racks.

Cartridge gripper

The iSWAP gripper mechanism has custom fingers specifically designed to handle the precise movement of the cartridges from the cartridge dispenser to insertion into the nexgen-MCS™ and dispose after testing.

Cartridge dispenser

The cartridge dispenser contains a removable lid to limit environmental exposure and can hold three stacks each of 20 cartridges and three desiccants (from multi-pack cartridge pouch) to ensure cartridge stability.

Endosafe® Nexus™ process flow

1. Analyst loads required cartridges, consumables, and samples on deck and starts software.
2. Barcode on sample tube is scanned for sample information and confirmed by analyst.
3. Robotic gripper adds cartridge to nexgen-MCS™ slot.
4. Pipetting arm adds sample to cartridge wells and 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 Nexus™ integrated software and can print or send to LIMS for further analysis.

Performance Data

Ideal for high-volume sample testing, the Nexus™ can handle water samples and perform dilutions for complex product matrices. It also reduces variability and the need for subsequent investigations (see Figures 3 and 4).

	Cartridge #	Sample Value (EU/mL)	Sample CV	Spike Recovery	Spike CV
0.5 EU/mL Endotoxin Standard	1	0.579	17.7%	81%	2.0%
	2	0.368	1.2%	97%	3.9%
	3	0.514	4.7%	121%	3.6%
	4	0.387	0.8%	100%	2.0%
	5	0.434	2.2%	115%	5.6%
	6	0.510	5.1%	147%	3.8%
	7	0.441	3.1%	104%	0.7%
	8	0.569	1.0%	127%	4.5%
	9	0.621	0.0%	148%	1.6%
	10	0.510	6.1%	121%	2.2%
	11	0.497	1.8%	107%	1.4%
	12	0.514	4.7%	138%	1.5%
	13	0.444	0.0%	80%	1.9%
	14	0.384	2.9%	136%	2.2%
	15	0.497	6.5%	132%	3.7%
	Average	0.485	3.9%	117%	2.7%
MAX	0.621	17.7%	148%	5.6%	
MIN	0.368	0.0%	80%	0.7%	

Figure 3. Performance data for the Endosafe® Nexus™ using standard curves prepared at 0.5 EU/mL Endotoxin Standard

	Cartridge #	Sample Value (EU/mL)	Sample CV	Spike Recovery	Spike CV
0.2 EU/mL Endotoxin Standard	1	0.177	1.8%	77%	0.6%
	2	0.193	3.2%	96%	5.5%
	3	0.154	1.7%	69%	6.0%
	4	0.237	3.1%	119%	9.3%
	5	0.196	0.3%	114%	3.9%
	6	0.204	3.9%	119%	4.0%
	7	0.153	2.6%	85%	9.3%
	8	0.175	1.2%	91%	0.6%
	9	0.161	1.2%	80%	5.7%
	10	0.176	1.5%	110%	1.3%
	11	0.222	4.0%	119%	6.0%
	12	0.174	2.7%	97%	2.4%
	13	0.148	4.6%	66%	4.3%
	14	0.237	4.5%	124%	4.7%
	15	0.213	3.0%	97%	0.0%
	Average	0.188	2.6%	98%	4.2%
MAX	0.237	4.6%	124%	9.3%	
MIN	0.148	0.3%	66%	0.0%	

Figure 4. Performance data for the Endosafe® Nexus™ using standard curves prepared at 0.2 EU/mL Endotoxin Standard

Endosafe® Nexus™ Service Programs

From regular maintenance and annual calibration to on-demand service contracts, our dedicated professionals are a single point of contact for all of your [Nexus™ 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.

Endosafe® Nexus™

Product Line	Product	Code
Endosafe® Nexus™	Nexus™ robotic system Nexus™ integrated software Computer Anti-static mat	MR550
	Nexus™ robotic system nexgen-MCS™ instrument Nexus™ integrated software Computer Anti-static mat	MR650
Endosafe® Nexus™ Accessories	Anti-static/slip mat	MR115
	Sterilized conductive 300 µL tips case (5,760 per case)	MR300
	Sterilized conductive 1 mL tips case (3,840 per case)	MR1000
	Tube racks, 24-position, shift & scan	MR2400
	Tube racks, 32-position, shift & scan	MR3200
Endosafe® Nexus™ Service and Support	Annual service	MR500
	Annual service: Full service	MR500FS
	IQ/OQ/PQ service	MR502
	On-demand repair services: Labor only	MR503
	On-site basic service	MR505
	Nexus™ software validation package	MR600

For spare or replacement parts, such as power cables and adapters, please contact your customer service representative.