The Endosafe® Nexus™
An Automated Robotic Solution for High-Volume Endotoxin Testing

The Endosafe® Nexus™ is the first fully automated robotic system designed specifically for endotoxin testing in the central QC lab, unlocking the full potential of the unique PTS™ cartridge technology. Ideal for high-volume water testing or samples that require dilutions, consistent testing with the Nexus™ reduces variability and the need for subsequent investigations. 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.

Performing endotoxin testing on large numbers of samples using traditional methodologies 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.

The Endosafe® Nexus™ eliminates the complications, lost time and potential for error associated with traditional high-volume endotoxin testing through its fully automated, cartridge-based technology. 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.

Click the image to view a video demonstration on how the Endosafe® Nexus™ can transform and simplify your endotoxin testing program.

Primary Components of the Nexus™
Disposable PTS™ Cartridges
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.

MCS™ Cartridge Reader
The 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.

EndoScan-V™ 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 efficiency.

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, precise air displacement pipetting and flexible deck layout make it ideal for central lab endotoxin testing.

Features

First fully automated system designed specifically for LAL testing

- Ties together LAL cartridge technology, multipack cartridges, fully automated liquid handling and simple data management

- 48-60 samples per run

- Small footprint: 30" H x 20" W x 54" L (76 x 51 x 137cm)

LAL Cartridge technology

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 μl of sample 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.

Air Displacement Pipetting

- Absence of a water-based pipetting system reduces risk of contamination or sample dilution (see Figure 1)

- High pipetting accuracy and precision from sub-μl to large (> 1 ml) volumes

- With no system liquids, diluters, valves or complicated tubing, no maintenance by the user is required

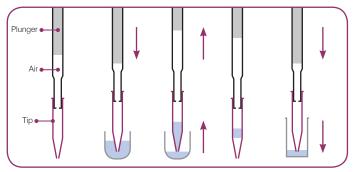- Liquid level detection to determine liquid levels in tubes

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.

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.
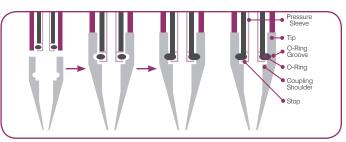

Figure 2. In the CO-RE technology, O-rings expand into grooves within the tip to secure it in place. Contracting the O-rings allows the tip to be ejected. This creates less stress on the system and improves perfromance.

Shift-and-Scan Bar Code

- Provides positive sample ID prior to inventory of samples
- Recognizes majority of current bar codes commonly used in the laboratory setting
- Current configuration:
    - 2 sample racks per deck containing either 12 mm-13 mm tubes (total of 60 samples on deck) or 15 ml Falcon tubes (total of 48 samples on deck)
    - Can 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 MCS™ and disposal after testing.

Cartridge Dispenser

- Single housing, holds 3 stacks of 20 cartridges
- Removable lid to limit exposure to environment
- Holds 3 desiccants (from multi-pack cartridge pouch) that ensure cartridge stability)

Nexus™ Process Flow

1. Analyst loads required cartridges, consumables and samples on deck and starts software
2. Bar code on sample tube scanned for sample information and confirmed by analyst
3. Analyst free to perform other lab responsibilities while Nexus™ starts testing (walk-away solution)
4. Robotic gripper adds cartridge to MCS™ slot
5. Pipetting arm adds sample to cartridge wells and prompts MCS™ to begin assay
6. When assay is complete, gripper takes cartridge out of MCS™ and discards into bin
7. Step 4 repeated until all samples are tested
8. Analyst reviews test results, which are tracked using EndoScan-V™ and can be printed or sent to LIMS for further analysis

Nexus™ Operational Benefits

- Nexus™ technology reduces variability and investigations
    - System provides highest level of precision and accuracy (see Figures 3 and 4 on the next page)
    - Fewer tests repeated due to operational errors (failure to add sample, correct volumes not dispensed, etc.)
- Fully automated — technician only needs to add bar-coded samples to deck
- Complete processing and entry of bar-coded samples
    - Reduces work load for busy technicians (set up and walk away)
    - Reduces errors associated with manual entry of product information
- Automated diluting (under development) and sample handling
    - Significantly reduces variability and subsequent investigations
    - Great for product testing requiring multiple dilutions
    - Robotics offer significant advantages over traditional microplate testing
    - No need for LAL rehydration or storage on deck
    - Standard curve preparation not required
    - Eliminates the need to modify robotic software scripts/templates

Performance Data

Cartridge #	Sample Value (EU/ml)	Sample CV	Spike Recovery	Spike CV
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%

(0.5 EU/ml Endotoxin Standard)

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
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%

(0.2 EU/ml Endotoxin Standard)

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

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