



MICROBIAL SOLUTIONS

Endosafe® nexgen-MCS™

Key Features

- Test up to five samples simultaneously
- Samples run independently, allowing for random access
- High throughput for real-time results
- Uses FDA-licensed Endosafe®-PTS™ cartridges
- USP/EP BET-compliant
- Four levels of cartridge sensitivity: 0.005 EU/mL, 0.01 EU/mL, 0.05 EU/mL, 0.10 EU/mL
- Results can be obtained via EndoScan-V™ version 5.5.5 or higher
- Utilizes new cartridge locking mechanism to ensure accurate cartridge positioning

The Endosafe® nexgen-MCS™ is a multi-cartridge endotoxin detection system that utilizes FDA-licensed Endosafe®-PTS™ cartridges for fast, quantitative, and accurate endotoxin results. The nexgen-MCS™ comprises five individual spectrophotometers built into a unit with a single Ethernet connector that links to a desktop computer running EndoScan-V™ version 5.5.5 or higher, our 21 CFR Part 11-compliant ready endotoxin-measuring software. This benchtop test system can test up to five samples in about fifteen minutes.

Test Technology

The nexgen-MCS™ uses LAL kinetic chromogenic methodology that measures color intensity directly related to the endotoxin concentration in a sample. The disposable cartridges used to run an assay contain precise amounts of LAL reagent, chromogenic substrate, and control standard endotoxin (CSE). The cartridges are manufactured according to rigid standard operating procedures promoting test accuracy, consistency, and product stability.

Test Procedure

To perform the test, the user simply pipettes 25 μ L of a sample (at a non-interfering dilution) into each of the four sample reservoirs of the cartridge. The reader draws and mixes the sample with the LAL reagent in two channels (the sample channels), and with the LAL reagent and positive product control in the other two channels (the spike channels). Lastly, the sample is mixed with a chromogenic substrate. After mixing, the change in color is measured and analyzed against an internally-archived standard curve.

EVERY STEP OF THE WAY

The nexgen-MCS™ can test five cartridges simultaneously, or any combination from one to five. Samples are run independently, allowing for random access. Multiple nexgen-MCS™ or portable nexgen-PTS™ units can be connected to a single PC for high throughput of samples with real-time results. By design, the cartridge automatically performs a duplicate sample/duplicate positive product control LAL test, thereby satisfying the harmonized USP/EP Bacterial Endotoxin Test (BET) for LAL testing.

FDA-Licensed LAL Assay

The cartridge used with the nexgen-MCS™ system is approved by the FDA for in-process and final product release testing of biomedical products. The nexgen-MCS™ can streamline testing in the QC laboratory by effectively troubleshooting multiple problematic products and getting a quick read on stat samples and raw materials while still being fully capable of performing routine release testing. The nexgen-MCS™ is designed to be compliant with global pharmacopoeial methods and meets the BET criteria for photometric techniques. When used in conjunction with the nexgen-PTS™, the nexgen-MCS™ is a highly efficient tool, enabling real-time endotoxin testing consistent with the FDA's PAT initiative. If using another endotoxin detection method, validation of products on the nexgen-MCS™ can be accomplished by performing inhibition/enhancement on three batches of product.

With the increasing demand for a high-throughput automated system, we incorporated our multi-cartridge technology into a simple, walk-away robotic solution with the Endosafe® Nexus™. Designed specifically for endotoxin testing in the central QC lab and high-volume water testing or samples that require dilutions, the Nexus™ offers the unique opportunity to reduce technician time and maximize lab space while decreasing test variability. Once the deck is fully loaded, no supervision is required.

Data Analysis

With the nexgen-MCS™, data reporting is simple. At the conclusion of the test, the endotoxin measurement and assay acceptance criteria are calculated by EndoScan-V™ and displayed on a computer screen. The instrument can be used to detect endotoxin levels as low as 0.005 EU/mL. Detailed reports can be generated from the nexgen-MCS™ through EndoScan-V™ version 5.5.5 and higher to Charles River Cortex™ for detailed data analysis and tracking and trending. Reports can also be generated and signed within Cortex™ if required.