



Endosafe[®]-MCS System

The Endosafe[®]-MCS is a multi-cartridge endotoxin detection system that utilizes FDA-licensed Endosafe[®]-PTS[™] cartridges and multiple spectrophotometers to provide endotoxin test results for up to five samples in about 15 minutes. The PTS[™] cartridges are the same as those used with our portable testing system.

Quantitative LAL results are captured via EndoScan-V[™], Charles River Laboratories' endotoxin detection software which is 21 CFR compliant for drugs, devices and biologics. The software provides detailed reports and can be linked to Endosafe[®] Microtrend for data trending and analysis.

Test Technology

The MCS system is comprised of five individual spectrophotometers built into a unit with a single USB connector that links to a desktop computer. The MCS uses LAL kinetic chromogenic methodology that measures color intensity directly related to the endotoxin concentration in a sample. 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 quality control procedures promoting test accuracy, consistency, and product stability.

Test Procedure

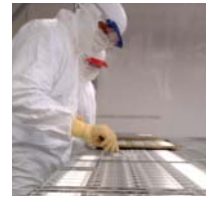
To perform the test, simply pipette 25 μ l of a sample into each of the four sample reservoirs of a cartridge. The reader draws and mixes the sample with the reagents. After mixing, the optical density of the wells is measured and analyzed against an internally-archived standard curve. By design, the cartridge automatically performs a duplicate sample/ duplicate positive product control LAL test, thereby satisfying the harmonized USP Bacterial Endotoxin Test (BET) and the FDA guideline for LAL testing.

Data Analysis

With the MCS, data reporting is simple. At the conclusion of the test, the endotoxin measurement and the assay acceptance criteria are calculated by EndoScan-V[™] and displayed on a computer screen. The instrument can be used to detect endotoxin levels as high as 10 EU/mL and as low as 0.01 EU/mL. Detailed reports can be generated from the MCS to Excel, LIMS and centralized databases.

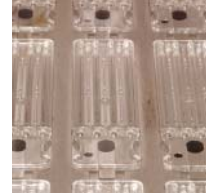
Advantages of Endosafe[®]-MCS

- Test multiple samples simultaneously
- Samples run independently allowing for random access
- High throughput for real-time results
- Single step, semi-quantitative LAL test
- Uses FDA-licensed PTS[™] endotoxin cartridges
- LAL test components all included in cartridges
- Three levels of sensitivity: 0.01 EU/mL; 0.05 EU/mL; 0.10 EU/mL
- Results can be tracked and trended via EndoScan-V[™] and Microtrend
- Sophisticated data management and reporting capabilities
- Samples can be traced to the individual spectrophotometer used to perform assay



FDA-Licensed LAL Assay

The cartridge used with the MCS system is approved by the FDA for in process and final product release testing. The 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 MCS is designed to be compliant with global pharmacopoeial methods and meets the BET criteria for photometric techniques. When used in conjunction with the Endosafe®-PTS™, the 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 the MCS can be accomplished by performing inhibition/enhancement on three batches of product.



The screenshot shows the PTS software interface with five assay stations. Each station has a table for inputting assay information and a section for reaction times and results.

Station	Cartridge Lot	Calibration Code	Product	Product Lot	Dilution	Reaction Times	Sample	Sample CV	Spike	Spike CV	Spike Recovery
PTS 1											
PTS 2											
PTS 3	6158140	507510508592	Product Name Here	12348	1						
PTS 4	6158140	507510508592	Product Name Here	12348	1						
PTS 5	6158140	507510508592	Product Name Here	12348	1	280 150 > 300 140	>0.006 EU/ml	5%	0.06 EU/ml	5%	120%

The MCS can test five cartridges simultaneously or one at a time. Samples are run independently allowing for random access. Multiple MCS or portable PTS™ units can be connected to a single PC for high throughput of samples with real-time results.

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