charles river

MICROBIAL SOLUTIONS

Endosafe® nexgen-PTS™

Cartridge Technology Applications:

- In-process sample testing
- Final drug product testing
- Nuclear medicine samples
- Dialysis samples
- Stem cell materials
- Pharmaceutical water systems
- Cleaning validations
- Medical devices
- Biomedical products
- Planetary protection (NASA)

The Endosafe® nexgen-PTS™ is a rapid, point-of-use handheld spectrophotometer that utilizes disposable cartridges for accurate, convenient, and real-time endotoxin testing, glucan concentration determination, and Gram identification. Using the same USP/BET-compliant test as the first-generation Endosafe®-PTS™, Charles River has implemented the advanced features of today's technology to address clients' needs for decreased assay run time, simplified data entry, reduced user variability, and enhanced administration control. The addition of a User Management function allows the nexgen-PTS™ to be 21 CFR Part 11 compliant ready. As with its predecessor, the flexible nexgen-PTS™ can be used in conventional quality control testing laboratories as well as at the point of sample collection. The system's portability and exceptionally fast results enhance testing programs and accelerate the drug development process.

Nexgen-PTS™ is fully compatible with Charles River Cortex™, our data management platform that provides an integrated solution to securely consolidate, query, and analyze all endotoxin data for internal QC and FDA-required trending reports. Providing a decentralized approach, Cortex™ allows for QA/QC control to manage all nexgen-PTS™ devices within the facility from one convenient location. This supports real-time data generation of critical in-process testing and the ability to compile data to make informed decisions about manufacturing processes rapidly and confidently.

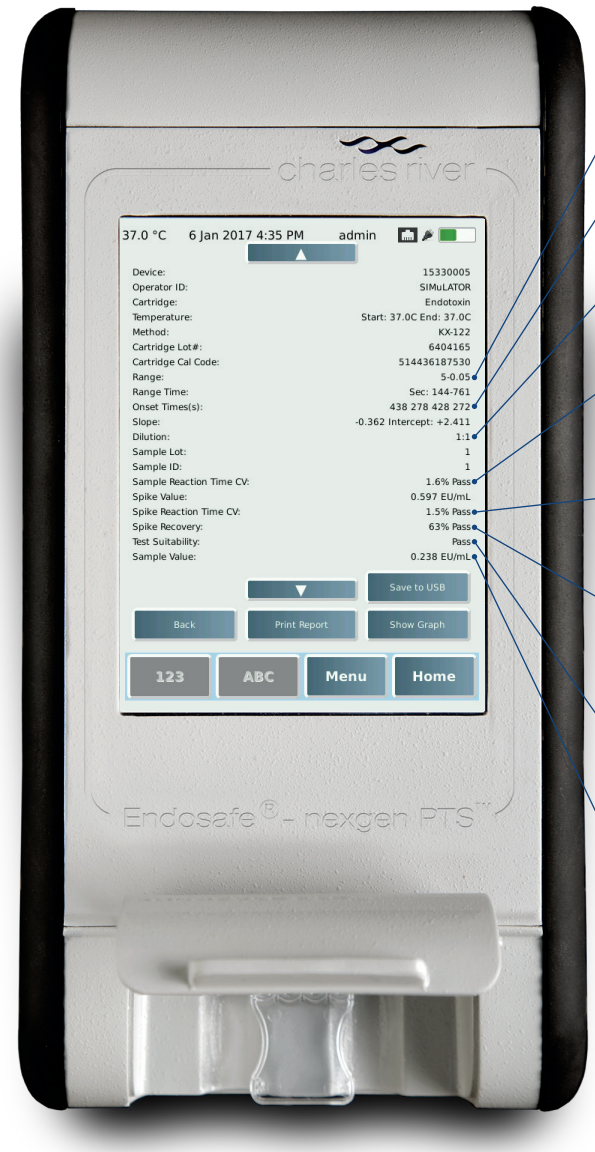
To perform a test using the nexgen-PTS™, the user simply pipettes 25 μL of a sample into each of the four sample reservoirs of the cartridge. The reader draws and mixes the sample with the LAL reagent in the sample channels in addition to the LAL reagent plus positive product control in the spike channels. The sample is combined with the chromogenic substrate then incubated. After mixing, the optical density of the wells is measured and analyzed against an internally archived standard curve. By design, the cartridge technology automatically performs a duplicate sample/duplicate positive product control LAL test, thereby satisfying the harmonized USP/EP bacterial endotoxin test (BET) for LAL testing. Results are displayed on the LCD screen and can be exported via Wi-Fi or Ethernet for printing and analysis in LIMS or Charles River Cortex™ software.

EVERY STEP OF THE WAY

What's Included

- Endosafe® nexgen-PTS™ instrument
- Ethernet cable
- Power supplies (US, EU, & UK)
- USB cable adapter
- Mini-pipettor

Interpretation of Results



Cartridge sensitivity range
Lambda = lowest value (0.05)

Reaction time of 4 channels
1 & 3 are sample channels,
2 & 4 are spiked channels

Dilution factor/Concentration
1 = neat, 10 = 1:10, 100 = 1:100,
or 0.1 mg/mL, 0.01 mg/mL, etc.

CV % of channels 1 & 3
Represents variation in reaction times of the two sample replicates
Must be < 25% for a valid test result

CV % of channels 2 & 4
Represents variation in reaction times of the two spiked replicates
Must be < 25% for a valid test result

Spike recovery
Represents % of spike that was recovered in channels 2 & 4
Must be between 50% and 200% for a valid test result

Test suitability
Evaluates sample CV, spike CV, and spike recovery for validity and assigns a Pass/Fail. "Pass" indicates a valid test and the sample value can be trusted

Reported EU value for sample (factoring in dilution)
If sample is non-reactive, EU value = lambda multiplied by dilution factor or lambda divided by concentration

Spike Recovery

The spike is a known amount of endotoxin that acts as the positive control. This control serves as a check for interference (inhibition and enhancement). Inhibition and enhancement are conditions that adversely alter the recovery of endotoxin in a test sample. Inhibition presents itself as less than 50% spike recovery, where enhancement is typically greater than 200%. For a valid assay, the spike recovery value must be between 50% and 200%, thus indicating no significant interference from the test sample.

Product Specifications

- Temperature control: 37°C ± 1°C
- Operating temperature range: Room temperature
- Warm-up time: 5-10 minutes from 20°C start
- Battery life: 3-5 hours of operation post-charge
- Dimensions: 254 mm x 137 mm x 70 mm
- Weight: 3 lbs. (1.36 kg)
- Data communication and device ports:
  - 10/100 base-T Ethernet with auto detect (RJ-45 connector)
  - Wireless 802.11 b/g (with internal antenna)
  - USB 2.0 (USB micro-B connector)

System Features

Touchscreen Display

The oversized LCD color touchscreen replicates the straightforward, intuitive style clients are accustomed to with their electronic devices outside of the lab. The luminous screen and easily identifiable menu icons enable seamless navigation throughout the system so users can progress through the testing steps quickly and with ease. The touchscreen uses pressure-based technology that allows for functionality with gloves, supporting sterile precautions and preventing LAL test contamination.

User Profile Management

With three levels of user management (i.e., administrator, manager, and user), user profiles can be established to grant appropriate access to system operators. Administrative rights allow access to the entire system, including setup and setting changes. Managers can access the product database and configure operators. Users are able to run tests and view and print reports. Password protection adds an extra level of security, as well as 21 CFR Part 11 compliance conformity, prompting for login credentials before accessing and performing system functions.

Barcode Scanning

The optional 1D/2D barcode scanner speeds operations by eliminating the need to enter sample input and cartridge certificate information manually. Simple, one-button automated scanning eliminates costly data entry errors and streamlines processes.

Real-Time Data Analysis

The nexgen-PTS™ offers heightened sensing optics for faster sample detection, with the ability to adjust the sample size detection between 20–30 μL†. In addition, the optimized sample centering places the sample in the best location for rapid measurement of the optical density of the wells. Operators can observe endotoxin measurement and assay acceptance criteria on the screen in real time, as data is analyzed. Final sample reaction data is likewise displayed on the screen and can be exported via USB, secure Wi-Fi, network-enabled printer, or automatically exported to Charles River Cortex™ software.

Enhanced Features for Reporting

With an internal storage capacity of over 8GB and expandable external USB storage, the nexgen-PTS™ can hold thousands of test reports. The newly added report restoration functionality makes it easy to access past reports through the test log and export them on demand for easier disaster recovery. Wireless capabilities allow for testing to be performed in a conventional quality control test laboratory setting or at the point of sample collection on the manufacturing floor, in addition to remote system access through Charles River Cortex™ for data export and printing*. The proprietary endotoxin detection software version 10.2 ensures users are in full compliance with the requirements of the FDA's 21 CFR Part 11, with an optional signature section on report printout.

† This function will need to be qualified by the end user in-house.

* Dependent on the type of the printer.

Cartridge Technology

The horseshoe crab-derived LAL reagent is the most sensitive and reliable method available for endotoxin testing, and with advancements in technology and decades of research and development, we've been able to greatly reduce the amount of LAL utilized in our proven cartridge technology. By using only 1/20th of the lysate compared to a traditional assay, this technology allows us to support humane practices and optimize our resources while reducing the impact on horseshoe crab populations.

Applications

FDA-Licensed LAL Cartridges

The nexgen-PTS™ utilizes the Endosafe®-PTS™ cartridges to perform a kinetic chromogenic assay that measures a color intensity directly related to the endotoxin concentration in a sample. Each cartridge contains precise amounts of LAL reagent, chromogenic substrate, and control standard endotoxin (CSE). Cartridges are manufactured according to rigid standard operating procedures, promoting test accuracy, consistency, and product stability. The cartridges are licensed by the FDA and accepted by USP/EP for testing raw materials and in-process samples as well as final products. The nexgen-PTS™ provides significant advantages over traditional LAL test methods while employing validated and proven LAL technology. The PTS™ cartridges, when used with the nexgen-PTS™ reader, can be used in the QC laboratory to effectively troubleshoot problematic products and to get a quick read on STAT samples and raw materials. The nexgen-PTS™ is designed for compliance with global pharmacopoeial methods and meets the BET criteria for photometric techniques.

Gram Identification Cartridges

Our Gram ID cartridge technology is a rapid assay that measures differences in the cell walls of microbial isolates. As an automated stain-free assay, the Gram ID cartridge eliminates technician variability that can occur in traditional Gram stain determination, which involves multiple reagent steps and interpretation of results. Technicians simply load a different isolate preparation into each of the four reservoirs of the disposable cartridge. The reader draws and mixes the sample and measures the optical density of the reaction. Within 3-7 minutes, results will indicate if the isolated organism is Gram negative bacteria, Gram positive bacteria, or yeast/mold and can effectively test organisms that are less than 72 hours old, reducing the need to subculture. The Gram ID cartridge is an objective assay that makes identifications based on the physiological composition of the cell walls, not on the uptake of dyes by organisms that have been fixed onto a microscope slide. This unique detection method reduces the opportunity for incorrect or Gram-variable results that occur due to varying physiological properties of the bacterial cell wall, thereby improving the accuracy of a Gram stain determination.

Glucan Assay Cartridges*

The glucan assay is a rapid, in-process test designed for investigational purposes to ensure that products do not contain (1,3)-β-D glucans. Glucans are known to cause false-positive results in LAL assays, which could trigger an investigation. Our glucan cartridges allows users to quickly and easily quantify Beta-glucans, leading to better process monitoring and faster out-of-specification (OOS) resolutions. The disposable glucan cartridges have a sensitivity range of 10-1,000 pg/mL, and yield results in approximately 30 minutes. This assay is in addition to the glucan blocking buffer that we offer for those compounds that are known in advance to have a strong possibility of containing Beta-glucans. The cartridge technology employs the Limulus enzyme cascade to detect (1,3)-β-D glucan in a sample. The cartridge and its interface with the reader have been designed to mimic kinetic chromogenic methods by measuring color intensity directly related to the (1,3)-β-D glucan concentration in a sample. Each cartridge contains precise amounts of glucan-specific LAL formulation, chromogenic substrate, and glucan standard.

*Cannot be used for diagnostic purposes.

charles river

askcharlesriver@criver.com • www.criver.com