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Endosafe® nexgen-PTS™

Our revolutionary Endosafe®-PTS™ streamlined endotoxin testing by condensing all the necessary reagents into a single, disposable FDA-licensed cartridge and made portable, real-time endotoxin testing a reality. Our customer-focused approach and passion for innovation has driven our refinement of this highly flexible technology, resulting in the development of the Endosafe® nexgen-PTS™.

The Endosafe® nexgen-PTS™ is a rapid, point-of-use handheld spectrophotometer that utilizes disposable cartridges for accurate, convenient and real-time endotoxin testing. Using the same USP/BET-compliant test as the first generation Endosafe®-PTS™, we've implemented the advanced features of today's technology to address your needs for decreased sample preparation time, simplified data entry, reduced user variability and enhanced administration control. 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 your drug development process.

Touch Screen Display

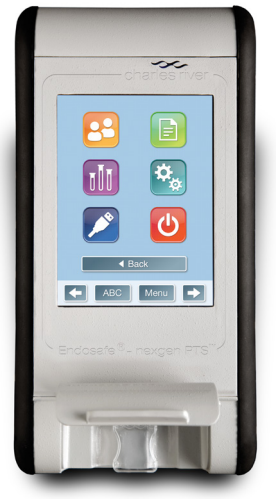
The oversized LCD color touch screen replicates the straightforward, intuitive style you are accustomed to with your electronic devices outside of the lab. The luminous screen and easily identifiable menu icons enable you to navigate seamlessly throughout the system, so you can progress through the steps of your testing quickly and with ease. The touch screen uses pressure-based technology which 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), you are now able to establish user profiles 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, prompting for login credentials before accessing and performing system functions.

Advantages of the Endosafe® nexgen-PTS™

- Cartridge technology detects between 0.005-10 EU/mL
- Quantitative LAL test results in 15 minutes
- USP/EP BET-compliant
- User-friendly portable system
- Improved software and heightened sensing optics for faster sample detection
- Enhanced processing power and expanded memory storage with an embedded operating system
- Designed for wireless capability for remote system access, data export and printing



Endosafe® nexgen-PTS™

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Barcode Scanning

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

Real-Time Data Analysis

The nexgen-PTS™ offers optimized sample centering to place the sample in the best location for rapid measurement of the optical density of the wells. You 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 screen and can be exported either through a USB, secure Wi-Fi, or network-enabled printer*.

Enhanced Features for Reporting

With an increased storage capacity of over 8 GB of internal storage and expandable external USB storage, the nexgen-PTS™ can hold thousands of reports. This makes it easy for you to access past reports and export them on-demand. Wireless capabilities allow you to perform testing in a conventional quality-control test laboratory setting or at the point of sample collection on the manufacturing floor.

FDA-licensed Cartridge Technology

The nexgen-PTS™ utilizes the pre-calibrated, disposable Endosafe®-PTS™ cartridges to perform a kinetic chromogenic assay which 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. Our 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. Approved by the FDA for in-process and final product release testing of biomedical products, 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.

Test Procedure

To perform the test, 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 two channels (the sample channels), and with the LAL reagent plus positive product control in the other two channels (the spike channels). The sample is incubated and then combined with the chromogenic substrate. 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 bacterial endotoxin test (BET) for LAL testing. Results are displayed on the LCD and can be exported via Wi-Fi or Ethernet for printing and analysis in LIMS.

**Dependent on the brand of the printer.*

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