

# ENDOSAFE® NEXGEN-PTS™

## ENDOTOXIN (LAL) DETECTION SYSTEM

THE BEST CHOICE FOR THE  
MEASUREMENT OF HIGH ACTIVITIES  
AND PET ISOTOPES

- FDA LICENSED
- RUNS ALSO ON BATTERY POWER
- MULTIPLE SENSITIVITY LEVELS AVAILABLE
- VERY EASY TO USE



The Endosafe® nexgen-PTS™ is a rapid, point-of-use test system that provides quantitative LAL results within 15 minutes. The nexgen-PTS™ utilizes LAL reagents in an FDA-licensed disposable test cartridge with a handheld reader for a completely contained, real-time endotoxin testing system. In addition to in-process and release testing, the nexgen-PTS™ can be used in the QC laboratory to get a quick read on raw materials and STAT samples that require immediate analysis. The flexibility of the nexgen-PTS™ allows it to be used in conventional, quality control testing laboratories as well as at the point of sample collection.

The nexgen-PTS™ is in line with the FDA's initiative for Process Analytical Technology (PAT), contributing to improved quality, safety and efficiency in the pharmaceutical manufacturing process. Training of new users is fast and easy and results are obtained quickly, preventing costly delays in research or production. It is the most commonly used device for Endotoxin detection in radiopharmaceutical production sites. The oversized touch screen display allows an easy and intuitive control of the equipment. The nexgen PTS™ features three password protected levels of user management, that grant appropriate access to system operators (administrator, manager and user). The system can hold thousands of reports thanks to its extended storage capacity. Elysia has fully integrated the Endosafe into the ARGUS-RPS system to improve the data transfer and storage. Uses FDA-licensed cartridges that are pre-loaded with all test components (USP/EP BET - compliant) The nexgen-PTS™ runs on battery power, so testing is portable. Quantitative results can be downloaded to a central PC for tracking and trending (wireless capability). Four levels of sensitivity are available as testing options: 0.005, 0.01, 0.05 and 0.10 EU/ml. No microbiology training is required; anyone can run this simple assay.

#### Technical Specifications

Temperature control	37° C + 1° C
Data interface	USB, secure Wi-Fi, network enabled printer (RJ-45)
Printer support	Thermal printer (Zebra printer)
Data storage	8Gb (thousands of report)
Power supply unit	100-240 V, 50-60 Hertz
Power supply on board	12 V DC, 5A
Battery life	4 - 6 hours of operation post-charge
Warm-up time	Approximately 5 -10 minutes from 20° C start
Display	Touch screen display LCD
Operating conditions	Temperature 15° to 27 ° C Humidity 10% to 85% noncondensing Altitude - unlimited

#### Endosafe® nexgen-PTS Cartridge Specifications

Reference package insert for storage requirements  
 Endotoxin Sensitivity: 10-0.1 EU/mL range, 5-0.05 EU/mL range, 1-0.01 EU/mL range, 0.5-0.005 EU/mL range  
 Rapid Micro Methods – Gram ID: Archived parameters for Gram-negative, Gram-positive and Yeast/Mold isolate identification  
 Inhibition/Enhancement Screening  
 Rapid Micro Methods – Glucan  
 Acceptable temperature: 37 °C + 1 °C  
 Sample requirement: 25 µL sample per channel

#### Consumables

##### PTS Inhibition/Enhancement screening cartridge

Inhibition/enhancement cartridges allow four samples or four dilutions of a sample to be tested on one cartridge to determine the presence of inhibition of enhancement. These cartridges do not detect endotoxin in the sample and only report a spike recovery value, so samples evaluated on I/E cartridges should be free of detectable endotoxin.

Kit of 10 cartridges  
 Storage temperature: 2-25 °C  
 Cartridges are for single-test use only  
 Shelf life: 2 years

##### PTS cartridge

Each Endosafe® - PTS cartridge contains four channels to which LAL reagent and a chromogenic substrate have been applied. Two of the four channels also contain an endotoxin spike, and serve as the positive product controls. The use of two Sample Channels and two Spike Channels is consistent with current USP photometric Limulus Amebocyte Lysate (LAL) methods. The PTS reader can be used to detect endotoxin in a variety of ranges.

Kit of 10 cartridges  
 Storage temperature: 2-25 °C  
 Cartridges are for single-test use only  
 Shelf life: 2 years

##### LAL reagent water (LRW)

LRW water that is free of detectable endotoxin and non-interfering to the assay.  
 Kit of 12 bottles (30ml bottle)  
 Storage temperature: 2-25 °C  
 Shelf life: 3 years

#### Physical specifications

Dimensions	D254 x W137 x H70 mm (D10.00" x W5.40" x H2.75")
Weight	1,36 kg (3 lbs) (without power supply unit)



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