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accelerating drug development. exactly.

Endosafe®-PTS™

Charles River Laboratories' newest endotoxin detection product, the FDA-licensed Endosafe®-PTS™, is a rapid, point-of-use test system that utilizes LAL reagents in a test cartridge with a handheld spectrophotometer. The PTS™ can effectively be used to obtain fast, quantitative LAL test results in any environment (a laboratory setting or at the point of sample collection). Since PTS™ assay results are available in about 15 minutes, the LAL testing of samples from multiple locations can be completed efficiently and accurately.

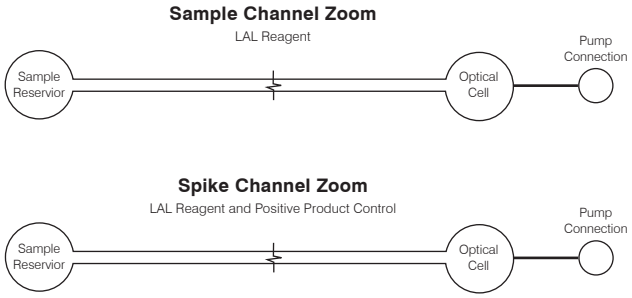
Test Technology

The PTS™ uses LAL kinetic chromogenic methodology that measures a color intensity that is directly related to the endotoxin concentration in a sample. Each cartridge contains 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, the user simply pipettes 25 µl of a sample into each of the four sample reservoirs of the cartridge (Figure 1). 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). 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 PTS™ 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.

Figure 1.



Advantages of Endosafe®-PTS™

- FDA-licensed
- Portable, handheld LAL test system
- Fast, quantitative results–anywhere
- Simple, one button operation
- Single step, quantitative LAL test
- Results in about 15 minutes
- LAL test components all included
- Detects between 0.01 - 10 EU/mL
- Data downloadable to a central PC

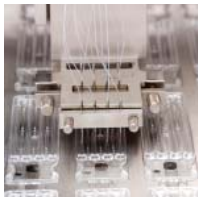
Assay Procedure

- Add 25 µl of sample to each of 4 channels in a cartridge
- Press enter
- Pump moves samples through cartridge (about 15 minutes)
- Optical cells are read kinetically at 395nm +/- 20nm
- Results displayed on screen

PTS™ Instrument Features

- Portable with re-chargeable power block
- Easy-to-read display screen
- Keypad operation
- Stores 100 test results
- Transfers data for formatting into standard reports
- Printable results
- Protective case with cover

FDA-licensed LAL Assay



The PTS™ was approved by the FDA as an alternative to traditional LAL testing methods for in-process and final product release testing of biomedical products. The PTS™ can be used in the QC laboratory to effectively troubleshoot problematic products and to get a quick read on STAT samples and raw materials that require immediate analysis. The PTS™ was designed to be compliant with global pharmacopoeial methods and meets the BET criteria for photometric techniques. Validation of the PTS™ can be accomplished by performing inhibition/enhancement on three batches of product.

Training of new users is fast and easy and results are obtained quickly–preventing costly delays in research or production. The Endosafe®-PTS™ provides significant advantages over traditional LAL test methods while still relying on validated and proven LAL technology.

Data Analysis

With the PTS™, data reporting is simple. At the conclusion of the test, the endotoxin measurement and the assay acceptance criteria are displayed on the screen. The instrument can be used to detect endotoxin levels as high as 10 EU/mL and as low as 0.01 EU/mL.

Internally, The PTS™ reader measures the reaction time in each channel. An archived standard curve specific for each batch of cartridges is constructed using the log of the reaction time vs. the log of the endotoxin standard concentration. The sample and spike values are calculated by interpolation off the standard curve using the reaction times.

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Contact Us

USA Tel: +1 (877) CRIVER-1 Email: endo-comments@crl.co
EUROPE Tel: 00 800 15 78 97 43 Email: eurendo@eu.crl.com
www.criver.com