



PTS™ for Endotoxin Detection

2007

PORTABLE TEST SYSTEMS

Charles River Laboratories received FDA approval for its handheld endotoxin testing system, the Endosafe®-PTS™. The innovative Portable Test System (PTS™) is designed to test LAL samples quickly and quantitatively, providing results in about 15 minutes. Now with FDA approval, the PTS™ can be used for in-process and final product release testing. The PTS™ is in line with the FDA's initiative for Process Analytical Technology (PAT) contributing to improved quality, safety, and efficiency in the manufacturing process. The PTS™ platform has been the foundation for new test technologies from Charles River, including a fast Gram identification method, the Endosafe®-PTS™ Gram ID, and a protein determination assay, the Endosafe®-PTS™ BCA™. The ease-of-use and portability of the PTS™ make it a suitable platform for future innovations in laboratory diagnostics.

Endosafe®-PTS™

The PTS™ is a rapid, point-of-use test system that utilizes LAL loaded into FDA-licensed disposable test cartridges that are prefilled with LAL. These cartridges are used with a hand held spectrophotometer. The PTS™ provides quantitative LAL test results in about 15 minutes and operates with a simple, one-button operation. Results are displayed on the screen and can be printed or downloaded for reporting and trending. The PTS™ mimics kinetic chromogenic LAL methodology by measuring color intensity directly related to the endotoxin concentration in a sample. The optical density is measured and analyzed against a lot-specific, internally archived standard curve. In keeping with USP BET photometric guidelines, the Endosafe®-PTS™ simultaneously performs testing in duplicate and averages the results.

The cartridges are manufactured in a GMP manufacturing area according to rigid quality control procedures promoting test accuracy and consistency.

Advantages of the PTS™

- Portable, hand held LAL test system
- Fast results at sample collection sites
- FDA-licensed test method
- Simple, one-button operation
- Single-step, quantitative LAL test
- Results in about 15 minutes
- All LAL test components included
- Detects between 0.01 – 1.0 EU/mL , 0.05 – 5 EU/mL, and 0.10 – 10 EU/mL
- Data downloadable to a central PC

PTS™ Product Applications

- Pharmaceutical product release samples
- Water systems
- Dialysis samples
- Nuclear medicine samples
- Release testing for medical devices
- Veterinary drugs
- Research samples
- In-process applications
- Cleaning validations
- Raw materials for medical devices — water, filters, medical-grade tubing



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Endosafe®-PTS™

		Code
Endosafe®-PTS™ instrument and integrated software	each	PTS100
Power supply		
Adapter cord		
Mini pipettor		
Operator manual		
PTS™ Package	each	PTS550
PTS™ instrument and integrated software		
Power supply		
Adapter cord		
Mini pipettor		
Operator manual		
4-year extended warranty		
Epson® printer		
IQ/OQ/PQ		

Endosafe®-PTS™ Cartridges*

		Code
0.1 EU/mL sensitivity		PTS201F
0.05 EU/mL sensitivity		PTS2005F
0.01 EU/mL sensitivity		PTS2001F

*Ten (10) cartridges per pack.

Endosafe®-PTS™ Cartridges* (unlicensed[†])

		Code
0.1 EU/mL sensitivity		PTS201
0.05 EU/mL sensitivity		PTS2005
0.01 EU/mL sensitivity		PTS2001

*Ten (10) cartridges per pack.

[†]These cartridges are not licensed by the FDA and may not be used for pharmaceutical release testing.

PTS™ Accessories

		Code
Mini pipettor (25 µL, disposable)	each	PTS400
Protective reader case	each	PTS600
Seiko® printer	each	PTS300
Epson® printer	each	PTS310
Endosafe®-PTS™ Inhibition / Enhancement Cartridge	10/Pack	PTS220

PTS™ Service Programs

Charles River provides a range of PTS™ Service Programs to protect against any future problems and to assist in the maintenance of the system. The programs are listed below. For additional program descriptions, please go to our web site at www.criver.com or call Technical Assistance at 1.800.762.7016.

PTS™ Service Programs

		Code
Annual calibration certification	each	PTS500
Extended warranty (four years)	each	PTS501
IQ/OQ/PQ	each	PTS502
On-demand repairs	each	PTS503



PTS™ Gram ID for Gram Identification

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PTS™ Gram ID for Gram Identification

The PTS™ Gram ID is a fast, simple test that measures differences in the cell walls of microbial isolates. The data is interpreted by the software to indicate whether a sample contains Gram negative or positive bacteria or to confirm a yeast/mold. The definitive, stain-free assay is a single-step test that provides Gram positive or negative results in about three minutes.

Gram Identification

As an automated test, the PTS™ Gram ID eliminates technician variability that can occur in traditional Gram stain determination which involves multiple reagent steps and interpretation of results. The PTS™ Gram ID 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 and thereby improves the accuracy of a Gram Stain determination. Over 90 microorganisms have been tested with the PTS™ Gram ID, proving the accuracy and specificity of the system.

Advantages of PTS™-Gram ID

- Determines Gram +, Gram -, and yeast/mold
- Gram + / - results in about 3 minutes
- Single-step, definitive test
- Simple, one-button operation
- Eliminates variability among technicians
- Greatly reduces Gram-variable results
- Runs four samples simultaneously
- Results can be printed and/or downloaded to a central PC

For pricing and product information, please call 1.877.CRIVER1.



The PTS™ Gram ID is a simple and efficient alternative to traditional Gram stain methods.



Endosafe®-PTS™ BCA™

The Endosafe®-PTS™ BCA™ assay is used to accurately determine protein concentration in laboratory samples. The PTS™ BCA™ builds upon the PTS™ platform, utilizing a hand held spectrophotometer and disposable cartridges to accurately determine protein concentrations. With the PTS™ BCA™, there is no need to prepare daily reagents or a standard curve — a time and cost savings advantage over traditional protein determination methods. The archived standard curve is available for either of the two standards — BSA and BGG.

PTS™ BCA™

BCA™ is one of the most popular methods for the colorimetric detection and quantitation of total protein. The protein to protein

variation with BCA™ is relatively low and it is compatible with samples that contain up to 5% surfactants. With PTS™-BCA™, the early onset of color is detected and measured at an absorbance of 562 nm. Samples can be added directly to the cartridge and the PTS™ instrument will measure the colorimetric change in each channel to quantify protein. Each cartridge is designed to test two samples in duplicate.

Advantages of PTS™ BCA™

- Results in 15 minutes or less
- No set up of standard curve necessary
- No incubation time required
- Minimal hands-on technician time
- Results can be printed and/or downloaded to a central PC

PTS™ BCA™ for Protein Determination

Endosafe®-PTS™ BCA™

		Code
Endosafe®-BCA™ Kit	each	PTS562
Instrument and integrated software		
Power supply		
Adapter cord		
Mini pipettor		
Operator manual		
Endosafe®-PTS™ BCA™ cartridge	10/pack	RMMBCA100
	100/pack	RMMBCA100

PTS™ BCA™ Accessories

		Code
Mini pipettor (25 µL, disposable)	each	PTS400
Protective reader case	each	PTS600
Seiko® thermal printer	each	PTS300
Epson® printer	each	PTS310

BCA is a trademark of Pierce Biotechnology, Inc.



Each BCA™ cartridge contains four channels of complete reagents to test two samples in duplicate.

2007