

Science + Technology = Confidence

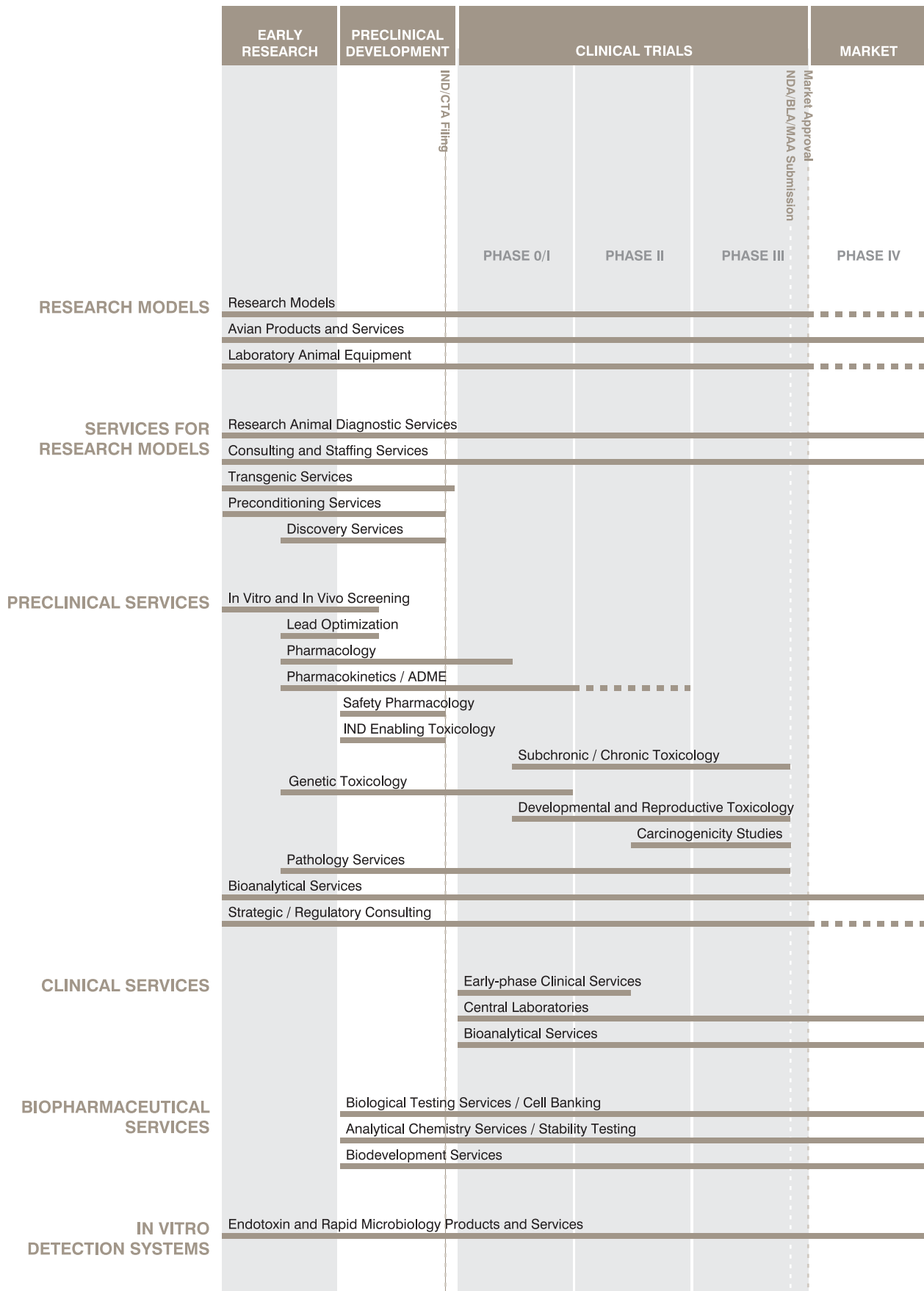


2008

Charles River Laboratories Endosafe® Products & Services
United Kingdom

CHARLES RIVER OFFERS A FULL RANGE OF PRODUCTS AND SERVICES TO HELP SUPPORT YOU ALONG THE RESEARCH, DISCOVERY AND DEVELOPMENT CONTINUUM.

RESEARCH, DISCOVERY AND DEVELOPMENT PROCESS



RAPID ENDOTOXIN DETECTION

- 2-7 Endosafe®-PTS™ (Portable Test System)
PTS™ Service Programs
Endosafe®-MCS (Multi-Cartridge System)
MCS Service Programs
PTS™ & MCS Disposable Cartridges
PTS™ & MCS Accessory Products

RAPID GRAM TESTING AND PROTEIN DETERMINATION

- 8-11 Endosafe®-PTS™ Gram ID
Endosafe®-PTS™ BCA
PTS™ BCA Cartridges and Accessories

LIMULUS AMEBOCYTE LYSATE (LAL) REAGENTS

- 12-15 Kinetic Turbidimetric LAL
Kinetic Chromogenic LAL
Gel-Clot LAL
Rapid Single Test Vial LAL
End-point Chromogenic Reagents

LIMULUS AMEBOCYTE LYSATE (LAL) ACCESSORY PRODUCTS

- 16-21 Control Standard Endotoxin
LAL Reagent Water
LAL Buffers
Endotoxin Indicators
Endotoxin-Free Test Tubes
Pipettes and Pipette Tips
96-Well Plates
PETG Bottles
Dispenser Tips

KINETIC LAL INSTRUMENTATION & SOFTWARE

- 22-27 EndoScan-V™ Endotoxin Software
Microtrend Software
Temperature Logger
Plate Readers and Accessories
Robotic System

CONTRACT TESTING SERVICES

- 28-31 Routine Endotoxin Determination
Routine Pyrogen Test
Methods Development
Product Validation
Product Release/Stability Testing
Reader/Software Qualification
Sample Preparation
Oven Depyrogenation Validation
Proficiency Testing Program

IN VITRO PYROGEN TEST

- 32-33 Endosafe®-IPT

RESOURCES

- 34-37 Terms & Conditions of Sale
Alphabetical Product Index
Contact Information

Charles River offers FDA-licensed products for rapid and traditional endotoxin testing. Our technical support services enable implementation of testing solutions easily and efficiently. New this year, our high-throughput, rapid testing system, the Endosafe®-MCS, builds on the strengths of our portable PTS™ system and permits analysis of multiple samples in 15 minutes.


Please contact us for more information at ukendo@eu.crl.com



Table of Contents

2008



A woman with short blonde hair, wearing a white lab coat, is shown in profile from the side, holding a white handheld device. The device has a screen and a circular opening. She is looking at the screen. The background is dark and out of focus.

The Endosafe®-PTS™
allows users to
achieve real-time
analysis with LAL
results available at
the point of sample
collection in about
15 minutes.



RAPID ENDOTOXIN DETECTION

The Endosafe®-PTS™ is a handheld endotoxin system that tests samples quickly and quantitatively, providing results in about 15 minutes. Used with FDA-approved disposable cartridges, the PTS™ can effectively be used for expeditious in-process and final product release testing, right at the point of sample collection. 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.

New this year, Charles River is proud to offer the Endosafe®-MCS, a multi-cartridge endotoxin detection system that tests up to five samples simultaneously. The samples run independently allowing for random access. Like the PTS™, the MCS provides endotoxin results in about 15 minutes using FDA-licensed cartridges.

Endosafe®-PTS™ and MCS Test Systems

The PTS™ and MCS are rapid test systems that utilize LAL loaded into FDA-licensed disposable test cartridges that are pre-filled with all of the reagents to run an LAL assay. These cartridges are used with the systems' built-in spectrophotometers to provide quantitative LAL test results in about 15 minutes with a simple, one-button operation. Results are displayed on the PTS™ screen or with the MCS, on the computer screen, and can be printed or downloaded for reporting and trending.



The FDA-licensed cartridges used with the MCS system are the same as those used with the Endosafe®-PTS™.

The systems mimic kinetic chromogenic LAL methodology by measuring colour 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/EP BET photometric guidelines, the Endosafe®-PTS™ and Endosafe®-MCS simultaneously perform testing in duplicate and average the results.

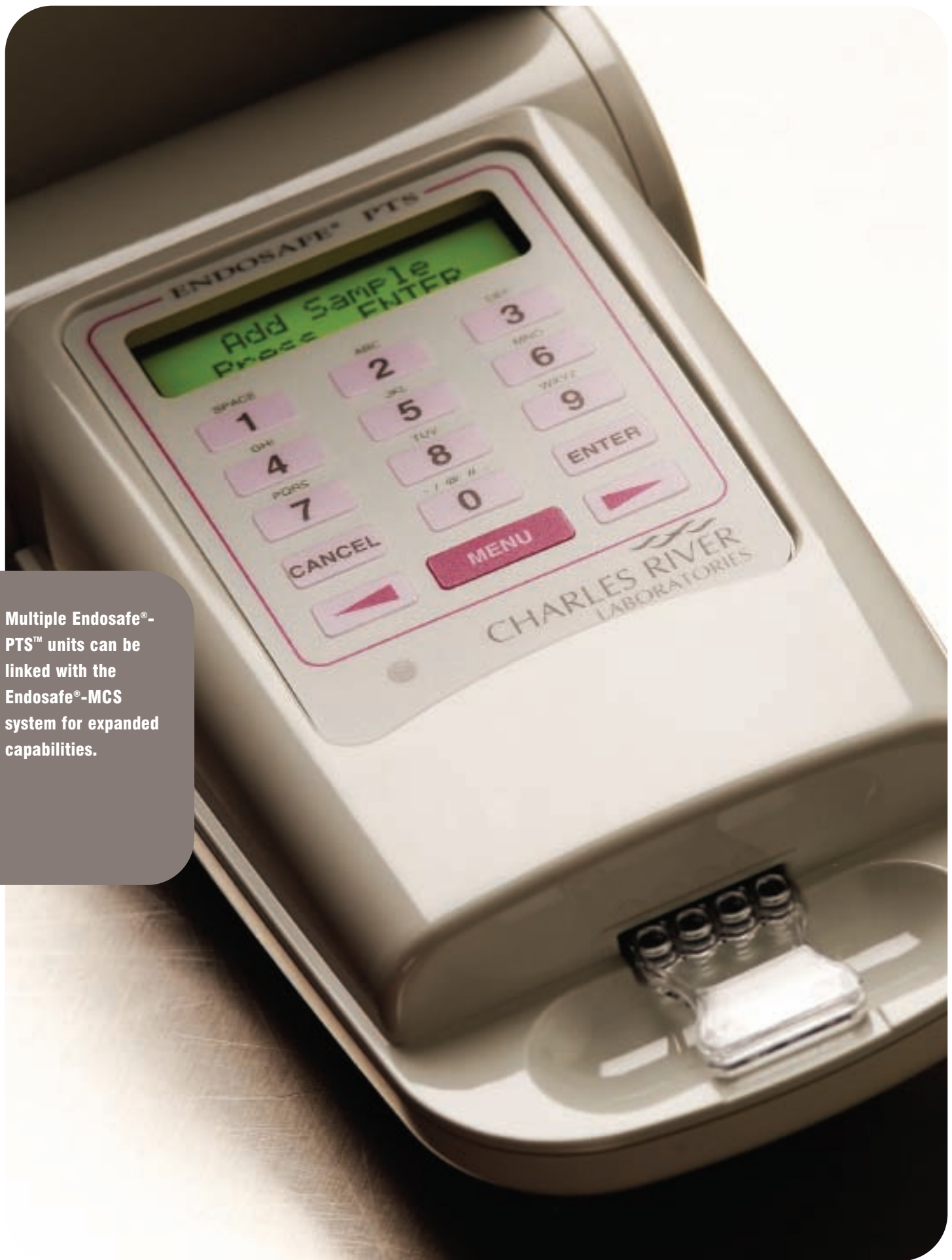
The cartridges used in the testing are manufactured in a GMP manufacturing area according to rigid quality control procedures promoting test accuracy and consistency.

Advantages of the PTS™ and MCS

- FDA-licensed cartridges
- Simple, easy operation
- Results in about 15 minutes
- Effective risk management tool
- Prevents bottlenecks and hold steps in test process
- Improves sample management programs
- Reduces number and cycle time of process
- Reduces downtime and improves efficiency
- All LAL test components included
- Detects between 0.01 – 1.0 EU/mL, 0.05 – 5 EU/mL, and 0.10 – 10 EU/mL

Rapid Endotoxin Detection

2008



Multiple Endosafe®-PTS™ units can be linked with the Endosafe®-MCS system for expanded capabilities.

ENDOSAFE®-PTS™ AND ENDOSAFE®-MCS



Endosafe®-PTS™ Instrument

The PTS™ is a portable, incubating spectrophotometer that comes equipped with software to run 15-minute endotoxin assays. For information on ordering disposable cartridges to use with the PTS™, please see page 7.

Endosafe®-PTS™ Instrument

	Code
Endosafe®-PTS™ instrument	PTS100
Integrated software	
Power supply	
Adaptor cord	
Mini pipettor	
Operator manual	
PTS™ Package	PTS550
PTS™ instrument and integrated software	
Power supply	
Adaptor cord	
Mini pipettor	
Operator manual	
4-year extended warranty	
Printer	
IQOQPQ	

Endosafe®-PTS™ Service Programs

Charles River provides a range of PTS™ service programs to protect against any problems and to assist in maintenance of the system.

Endosafe®-PTS™ Service Programs

	Code
Annual calibration certification	PTS500
Extended warranty* (four years)	PTS501
IQOQPQ qualification package	PTS502
Performance qualification (PQ) service*	TS502
On-demand repairs	PTS503
PTS™ rental (one month)	MF100

*Service must be purchased within the first year for eligibility.

Endosafe®-MCS Instrument

The MCS system permits five endotoxin determinations to be completed in 15 minutes when used with disposable PTS™ LAL cartridges. The system allows random access of samples and links to EndoScan-V™ and Microtrend for sample tracking and trending.

Endosafe®-MCS Instrument

	Code
Endosafe®-MCS instrument	MCS100
Integrated software	
Power supply	
Operator manual	

Endosafe®-MCS Service Programs

Charles River provides a range of MCS service programs to protect against any problems and to assist in maintenance of the system.

Endosafe®-MCS Service Programs

	Code
IQOQPQ qualification package	MCS502
Performance Qualification (PQ) service	TS502
On-demand repairs	MCS503

Endosafe®-PTS™ and Endosafe®-MCS

2008



Each PTS™ cartridge contains precise amounts of reagents and is manufactured according to rigid quality control procedures to ensure test accuracy and product stability.

PTS™ / MCS CARTRIDGES AND ACCESSORY PRODUCTS

The PTS™ and MCS readers utilize the same disposable cartridges for easy, 15-minute endotoxin testing. Cartridges are available for FDA licensed testing or unlicensed testing. New this year, we have added 5-packs of cartridges for improved efficiency and economics. Please keep in mind that cartridges should be used shortly after opening the pouch.

Endosafe®-PTS™ Cartridges - Pack of 10 cartridges individually pouched*

Sensitivity EU/mL	Code
0.1	PTS201F
0.05	PTS2005F
0.01	PTS2001F

*Licensed by the FDA.

Endosafe®-PTS™ Cartridges (unlicensed)† - Pack of 10 cartridges individually pouched

Sensitivity EU/mL	Code
0.1	PTS201
0.05	PTS2005
0.01	PTS2001

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

Endosafe®-PTS™ Cartridges - Case of 25 cartridges, 5 per pouch*

Sensitivity EU/mL	Code
0.1	PTS551F
0.05	PTS5505F
0.01	PTS5501F

*Available upon licensing by the FDA.

Endosafe®-PTS™ Cartridges (unlicensed)† - Case of 25 cartridges, 5 per pouch

Sensitivity EU/mL	Code
0.1	PTS551
0.05	PTS5505
0.01	PTS5501

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

Inhibition/Enhancement Cartridges* - Pack of 10 cartridges individually pouched

	Code
Inhibition/Enhancement cartridges	PTS220

*For checking the product PPC recovery of 4 different dilutions.


PTS™ Accessories

	Code
Mini pipettor (25 µL, disposable)	PTS400
Eppendorf® 25 µL pipettor	PTS700
Eppendorf® tips, (1-200 µL, 100/pack, individually wrapped)	D200
Protective reader case	PTS600
Seiko® thermal printer	PTS300
Thermal paper for Seiko® thermal printer	PTS301
Printer cable	PTS302
Epson® dot matrix printer	PTS310
Paper roll for Epson® printer	PTS313
Ribbon for Epson® printer	PTS312
PC cable	PTS108



PTS™/ MCS Cartridges and Accessory Products

2008



The Endosafe®-PTS™ system can be used for real-time endotoxin detection and Gram identification.

PTS™ GRAM ID FOR GRAM IDENTIFICATION

Endosafe®-PTS™ Gram ID

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/mould. 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 micro-organisms have been tested with the PTS™ Gram ID, proving the accuracy and specificity of the system.

Advantages of PTS™ Gram ID

- Determines Gram +, Gram – results
- Confirmation of yeasts and moulds
- 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 00800 15789743 (Toll free) or send an email to ukendo@eu.crl.com




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



PTS™ Gram ID for Gram Identification

2008



The Endosafe®-PTS™ BCA assay utilizes a “handheld” reader and disposable cartridges to determine protein content quickly and efficiently.



PTS™ BCA FOR PROTEIN DETERMINATION

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 quantification

of total protein. The protein to protein variation with BCA is relatively low and is compatible with samples that contain up to 5% surfactants. With PTS™ BCA, the early onset of colour 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

- Consistent with FDA's PAT initiative
- Results in about 20 minutes
- 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

Endosafe®-PTS™ BCA Instrument

	Code
Endosafe®-PTS™ BCA instrument Reader and integrated software Power supply Adaptor cord Minipipettor Operator manual	PTS562
Endosafe®-PTS™ BCA package PTS™ instrument and integrated software Power supply Adaptor cord Mini pipettor Operator manual 4-year extended warranty Printer IQQQPQ	RMMBCA550

PTS™ BCA Cartridges

	Packaging	Code
PTS™ BCA cartridges	10/pack	RMMBCA10
	100/pack	RMMBCA100

PTS™ BCA Accessories

	Code
Minipipettor (25 µL disposable)	PTS400
Eppendorf® 25 µL pipettor	PTS700
Eppendorf® pipette tips (1-200 µL, 100 per pack, individually wrapped)	D200
Protective reader case	PTS600
Seiko® thermal printer	PTS300
Thermal paper for Seiko® thermal printer	PTS301
Printer Cable	PTS302
Epson dot matrix printer	PTS310
Paper roll for Epson printer	PTS313
Ribbon for Epson printer	PTS312
PC cable	PTS108

PTS™ BCA for Protein Determination

2008

Charles River's LAL formulation provides enhanced stability, sensitivity, speed and linearity as well as greater interference resistance for optimized test performance.





LAL REAGENTS

Limulus Amoebocyte Lysate (LAL) is the most sensitive and specific means available to screen drugs, biologics, medical devices, and raw materials for the presence of endotoxin. Our optimized formulations provide increased sensitivity, greater linearity, and superior interference resistance.

Our LAL reagents are licensed by the Food and Drug Administration for product release.

Kinetic Turbidimetric LAL

Kinetic Turbidimetric (KTA) reagents yield quantitative endotoxin values when used with a multi-tube or microplate reader equipped with endotoxin measuring software. Both KTA and KTA² are buffered to provide significant interference-resistance properties. KTA is licensed for both kinetic and gel-clot analyses and permits a direct correlation between methods.

KTA², a second generation kinetic turbidimetric LAL, offers faster reaction times and has a wider standard curve range (0.001 – 50 EU/mL). The superior turbidimetric formulation of KTA² offers the performance of kinetic chromogenic LAL at turbidimetric prices.

Kinetic Turbidimetric LAL

KTA (5.2 mL vial)

	Sensitivity EU/mL	Code
KTA ²	50-0.001	R19000
KTA	50-0.005	R15015
	50-0.005	R15003
	50-0.005	R15006

Endochrome-K™ LAL

Endochrome-K™ is a quantitative chromogenic LAL test that contains a colourless substrate and LAL co-lyophilized into a single, stable reagent. The unique stability of our reconstituted LAL allows for extended bench time and -20°C storage and reuse. Multiple packaging options are available and include a kit format or bulk packaging.

Endochrome-K™ LAL

	Sensitivity EU/mL	Code
Endochrome-K™ 256 test kit 8 x 3.2 mL vials 2 x 10 ng control standard endotoxin 3 x 30 mL LAL reagent water	50-0.005	R1708K
Endochrome-K™ 320 tests 10 x 3.2 mL vials	50-0.005	R1710K
Endochrome-K™ 3200 tests 100 x 3.2 mL vials	50-0.005	R17100K

KTA, KTA², and Endochrome-K™ LAL Reagents

2008

Charles River's highly efficient, automated production systems allow for significant quantities of LAL and accessory products to be manufactured according to our strict quality guidelines.





Gel-Clot LAL

The gel-clot assay is a simple, qualitative method best used for biologics and dialysis clinics and small, low-volume laboratories. Endosafe® lysate features a firm gel over a wide range of sensitivities. The reagent is buffered for better interference-resistance.

Gel-Clot LAL

50-Test Vial (5.2 mL)

Sensitivity EU/mL	Code
0.015	R15015
0.03	R15003
0.06	R15006
0.125	R11012
0.25	R11025

10-Test Vial (1.2 mL)

Sensitivity EU/mL	Code
0.03	R12003
0.06	R12006
0.125	R12012
0.25	R12025

Single-Test Vial (0.2 mL)

Sensitivity EU/mL	Code
0.03	R13003
0.06	R13006
0.125	R13012
0.25	R13025

**Not available in Europe.*

Rapid Single Test Vial (0.2 mL)*

	Code
Rapid single test vial (50-test)	R135001
Rapid positive product control (50-test)	PC200

**This product is not licensed by the FDA and may not be used for pharmaceutical release testing.*

End-Point Chromogenic Reagents


The end-point chromogenic reagent performs as a non-kinetic LAL assay and yields quantitative results quickly over a narrow standard curve range, without the need for an incubating plate reader.

End-Point Chromogenic Reagents

	Sensitivity EU/mL	Code
Endpoint chromogenic kit - 140 tests	1.2-0.15 or 0.12-0.015	R160

Gel-Clot, Rapid STV, and End-Point LAL Reagents

2008

A photograph showing four glass vials with white caps, arranged in a white plastic rack. The vials are slightly tilted and contain a clear liquid. The background is a soft, out-of-focus light blue and white. The vials are positioned in the upper half of the frame, with the rack extending downwards.

Charles River's LAL reagents, accessory products, and kinetic instrumentation are optimized to provide greater consistency and accuracy for LAL testing programs.



LAL ACCESSORY PRODUCTS

One of the most common reasons for inconsistent LAL results is contamination and interference associated with uncontrolled accessories. Charles River supplies all the necessary accessory products required to run an LAL test, shipped with Certificates of Quality certifying appropriate endotoxin levels.

Control Standard Endotoxin (CSE) *E. coli*

	Packaging	Code
CSE 500 ng per vial*	one vial	E110
CSE 10 ng per vial*	one vial	E120
Positive control (for single test)	25/pack	PC100

*Lot-specific Certificate of Analysis included.

CXE Kit*

	Code
CXE Extended CSE Dilution Kit 1 x 10 ng Control Standard Endotoxin 1 x 60 mL stabilizing solution 1 x 11 packs of 16 x 100 mm capped tubes	E140

*Lot-specific Certificate of Analysis included.

LAL Reagent Water (in Plastic Bottle)

	Packaging	Code
30 mL bottle (<0.005 EU/mL)	12/pack	W130
50 mL bottle (<0.005 EU/mL)	12/pack	W120
100 mL bottle (<0.005 EU/mL)	12/pack	W110
500 mL bottle (<0.005 EU/mL)	6/case	W150

LAL Buffers†

	Packaging	Code
30 mL 0.1 M Tris buffer	12/case	BT103
5 mL 0.25 M Tris buffer	6/pack	BT101
5.5 mL Endotoxin-Specific buffer	6/pack	BG120
4 mL 1 M MgSO ₄ 0.5 M Tris buffer	6/pack	BC1000
30 mL Bio-dispersing agent	12/case	BD100

†Please contact Technical Assistance before using buffers. Additional buffers are available for specific testing needs.

Endotoxin Indicators**


	Code
2,000 EU	EVV2K
10,000 EU	EVV10K
100,000 EU	EVV100K
1 million EU	EVV1M
2.5 million EU	EVV2.5M
10 million EU	EVV10M

**For dry heat oven validations.

**Not available for Europe.

LAL Accessory Products

2008



**Endosafe® Rapid
LAL Single Test Vials**
are routinely used for
endotoxin detection in
research samples,
renal dialysis process
water, and dialysate
solutions.



LAL Accessory Products

2008

Depyrogenated and Endotoxin-Free Certified Test Tubes

Reaction Tubes

	Packaging	Code
10 x 75 mm capped soda glass tubes in a box	50/pack	T100
10 x 75 mm soda glass tubes wrapped in aluminium foil	50/pack	T200
10 x 75 mm borosilicate glass tubes wrapped in aluminium foil (appropriate for use with tube readers)	50/pack	T400
8 x 75 mm borosilicate glass tubes wrapped in aluminium foil (only for use with tube readers)	50/pack	T500
10 x 75 mm, screw capped borosilicate glass tubes in a box	50/pack	TL1200

Dilution Tubes

	Packaging	Code
12 x 75 mm borosilicate glass tubes wrapped in aluminium foil	50/pack	TL1000
13 x 100 mm borosilicate glass tubes wrapped in aluminium foil	50/pack	T300
16 x 90 mm screw capped borosilicate glass tubes in a box	70/pack	TL700

Sampling Tubes

	Packaging	Code
18 x 150 mm borosilicate glass tubes wrapped in aluminium foil	14/pack	T600
16 x 160 mm, screw capped borosilicate glass tubes in a box	100/pack	TL800



Charles River offers a full line of accessory products that are certified to be endotoxin-free to support trouble-free testing.



At Charles River,
we bring our
customers innovative
products that make
testing faster
and more flexible.



LAL Accessory Products

2008

Depyrogenated Glass Pipettes

	Packaging	Code
1 mL wrapped in aluminium foil	5 packs of 10	P100
2 mL wrapped in aluminium foil	5 packs of 10	P200
5 mL wrapped in aluminium foil	5 packs of 10	P500
10 mL wrapped in aluminium foil	5 packs of 10	P1000

Pipette Tips

	Packaging	Code
5-200 μ L Eppendorf® pipette tips (individually wrapped)	50/pack	D100
5-200 μ L Eppendorf® pipette tips (individually wrapped)	100/pack	D200
5-200 μ L pipette tips (individually wrapped)	500/pack	DF400
100-1000 μ L pipette tips (individually wrapped)	250/pack	DF500
5-200 μ L pipette tips (96 racked)	10 racks/pack	DF700
100-1000 μ L pipette tips (96-racked)	10 racks/ pack	DF800

*Not Available in Europe.

96-Well Individually Wrapped Endosafe® Plates*

	Packaging	Code
96-well polystyrene plate (certified to 0.05 EU/mL)	Each	M905
96-well polystyrene plate (certified to 0.05 EU/mL)	50/case	M905
96-well polystyrene plate (certified to 0.005 EU/mL)	Each	M9005
96-well polystyrene plate (certified to 0.005 EU/mL)	50/case	M9005

*Tissue cultured treated.

**Not Available in Europe.

Validated Reservoir for Mixing Reagent Vials

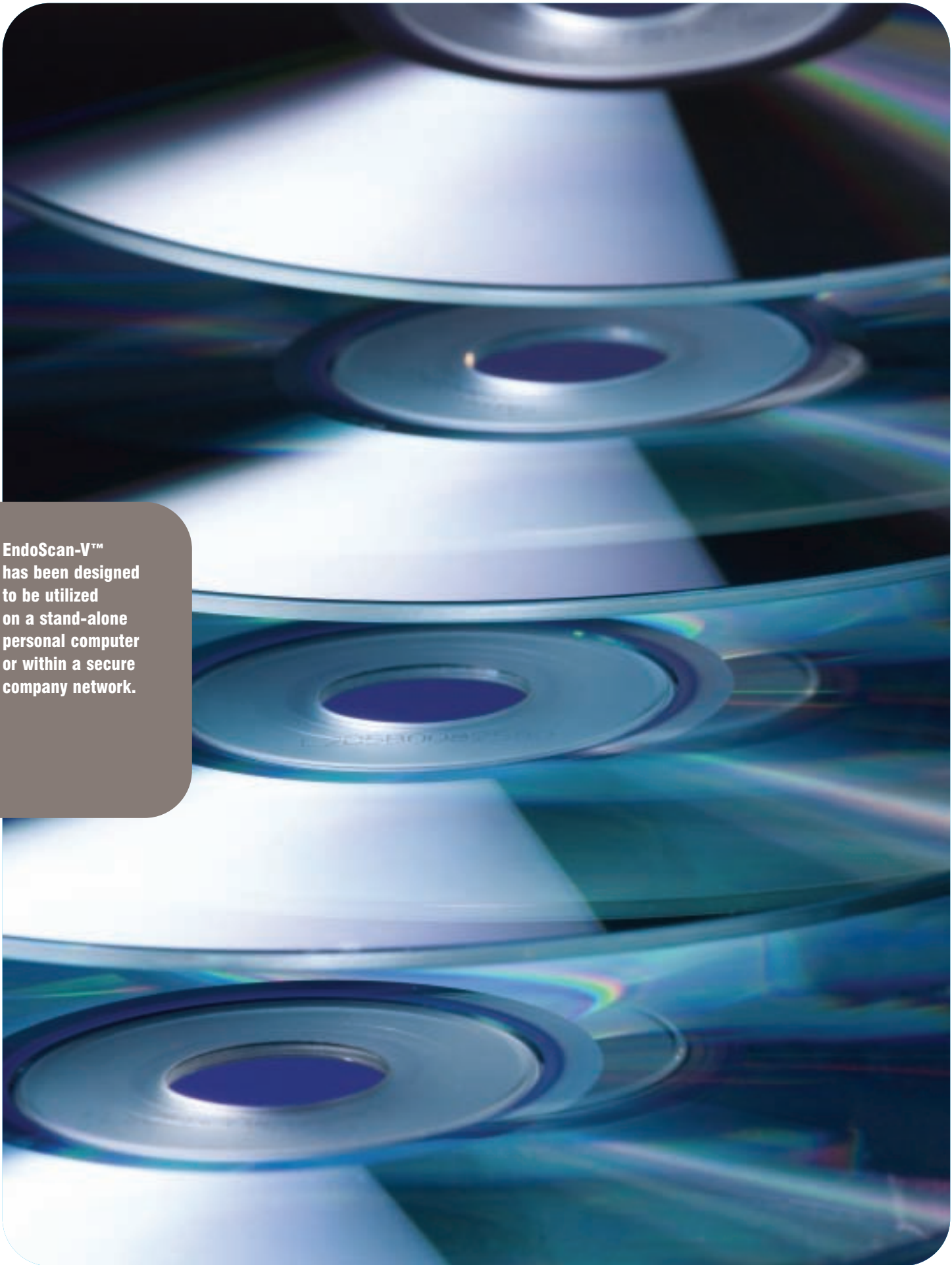
	Packaging	Code
50 mL reservoirs (individually wrapped)	80/pack	F80

Validated PETG Bottles for LAL Sampling

	Packaging	Code
30 mL bottles	24/pack	F1030
60 mL bottles	24/pack	F1060
125 mL bottles	24/pack	F1125
250 mL bottles	24/pack	F1250
500 mL bottles	24/pack	F1500
1000 mL bottles	24/pack	F1000
2000 mL bottles	24/pack	F2000

Dispenser Tips

	Packaging	Code
Tips - 0.5 mL, individually wrapped	100/box	PF1600
Tips - 2.5 mL, individually wrapped	100/box	PF1800
Tips - 5 mL, individually wrapped	100/box	PF1900



EndoScan-V™
has been designed
to be utilized
on a stand-alone
personal computer
or within a secure
company network.



ENDOSCAN-V™ AND MICROTREND SOFTWARE

EndoScan-V™ is compatible with a variety of microplate and tube readers and with the Endosafe®-PTS™ and Endosafe®-MCS systems. Microtrend, our database trending software specific for LAL testing is also available. EndoScan-V™ and Microtrend design allows the end user to easily comply with regulations for software validation and applicable electronic records requirements

Endosafe® EndoScan-V™ Software

EndoScan-V™ has been verified and validated to be consistent with FDA requirements. It performs the requisite calculations and creates batch reports for product release. For added protection, it generates secure data files and audit trails on all actions involving files and test data. The program was designed with flexible configuration capabilities for networking and performance options for gaining operational efficiencies.

Features of EndoScan-V™

- Click and drag functions for fast and easy template setup
- User-defined database for selection of validated test parameters
- Help section with regulations, user manual, and published endotoxin limits
- Flexible exporting function from supported readers that facilitates interfacing with trending software, Excel™, LIMS, and centralized databases
- Enhanced security features
- Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) packages available
- Available in English, French and German

Endosafe® Microtrend Software

Microtrend is the next generation data-trending package from Charles River Laboratories. Microtrend leverages the power of Structured Query Language (SQL) to provide a comprehensive trending tool that tracks and trends LAL test data. Microtrend can be tailored to meet a range of objectives, from creating simple and complex queries to distributing and displaying illustrated results across a network to facilitate an in-depth review of available data. The software works in conjunction with EndoScan-V™ 3.1.4 or higher to organize and analyze data. Data from EndoScan-V™ is exported directly to Microtrend for analysis. EndoScan-V™ provides additional fields to allow accessory materials and test samples to be tracked and queried by Microtrend.

Features of Microtrend

- Compiles, organizes, and analyzes historical LAL testing data
- Eliminates the need to input data into a spreadsheet program for analysis
- Allows viewing of imported data over a period of time to observe trends in production
- Monitors results at the system level or isolates subsystems for detailed analysis
- Trends standard curve data by reaction times or by back-calculated endotoxin values
- Monitors proficiency of analysts

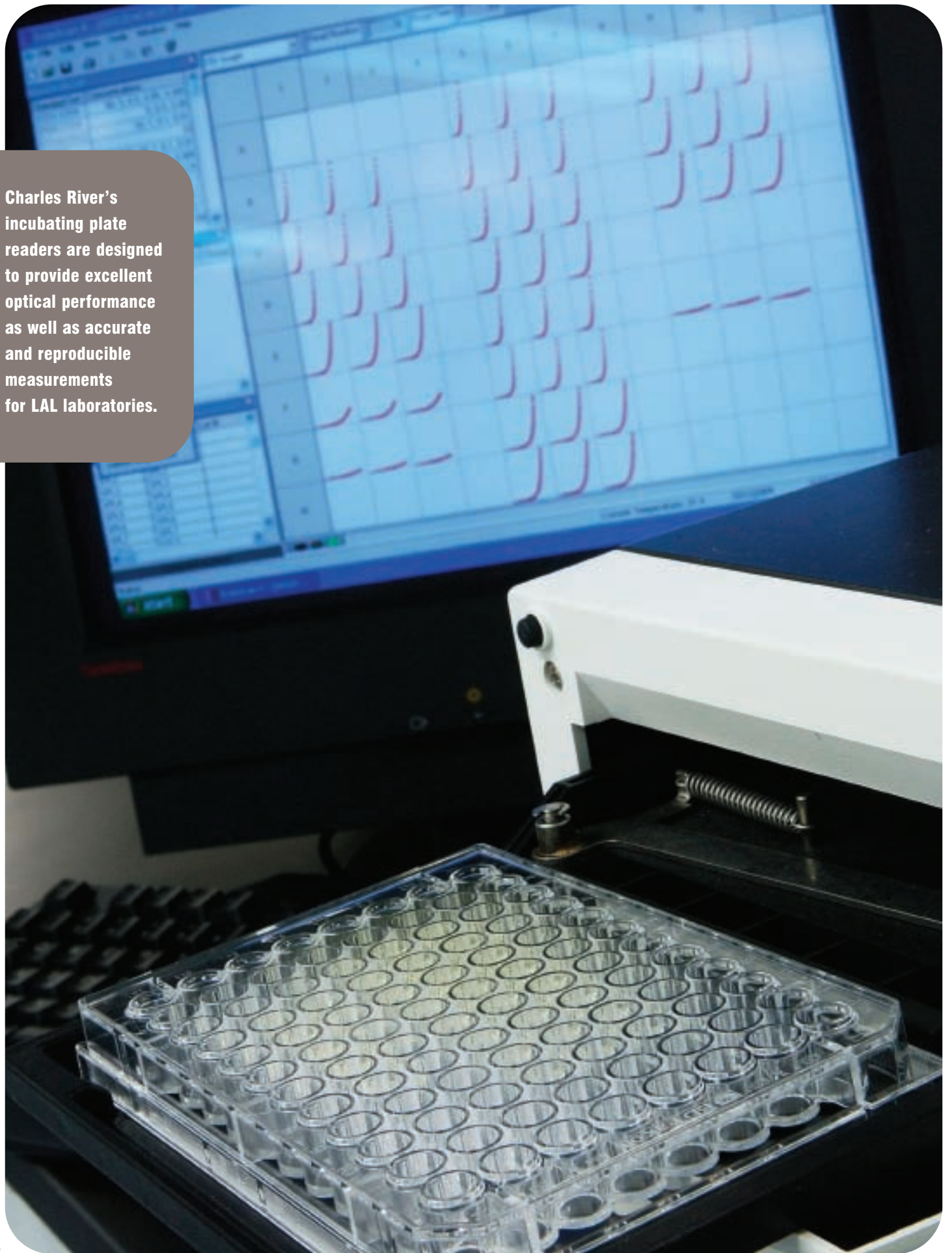
Endosafe® Software

	Code
Endosafe® EndoScan-V™ endotoxin measuring software (compatible with Bio-Tek® and Tecan™ plate readers, tube readers, PTS™ and MCS)	M1200
EndoScan-V™ software validation package	TS600
Microtrend database trending software (compatible with Bio-Tek® and Tecan™ plate readers, tube readers, PTS™ and MCS)	M804
Microtrend software validation package	TS1000

EndoScan-V™ and Microtrend Software

2008

Charles River's incubating plate readers are designed to provide excellent optical performance as well as accurate and reproducible measurements for LAL laboratories.





Endosafe® Kinetic Plate Readers

2008

Endosafe® Kinetic Plate Readers

Charles River's LAL reagents and software are compatible with several plate and tube readers. The plate readers are compact, multi-use spectrophotometers that offer superior temperature uniformity and excellent optical performance. The readers offered, manufactured by Tecan™ and Bio-Tek®, instruments, both world leaders in the area of diagnostic equipment, are capable of running kinetic and end-point LAL assays, as well as general applications such as ELISAs. Charles River provides technical support for our plate readers, including on-site annual calibration with a service contract agreement and on-site user training.

Endosafe® Temperature Logger

The Endosafe® Temperature Logger (ETL) is used for the validation of temperature uniformity in incubating microplate readers. The ETL makes it possible to accurately validate temperature uniformity within the microplate chamber of a spectrophotometer, replacing the cumbersome method of attaching thermocouples to the microplate wells. With the ETL, the reader drawer can be closed for more precise readings.

Endosafe® Temperature Logger

	Code
Endosafe® Temperature Logger (ETL) Package Includes : ETL temperature data-logging software, microplate, interface connections, software operating manual and certificate of calibration	MT400
Temperature evaluation of plate reader using the ETL*	TS801

*Travel expenses applicable.

Tecan™ Kinetic Plate Readers and Accessories

	Code
Sunrise™ incubating microplate reader (with 340,405,450,620 nm filters)	MS200
QC PAC 2 calibration plate for Sunrise™ reader	MS400
Calibration plate recertification (valid for one year)	TS3000
Bulb	M700/S

Bio-Tek® Kinetic Plate Readers and Accessories


	Code
Bio-Tek® incubating microplate reader (with 340,405,450,490,630 nm filters)	M200
Calibration plate for Bio-Tek® reader	M400
Calibration plate recertification (valid for one year)	TS3000
Bulb	M700

Plate Reader Options

	Code
Service contract for reader*	TS2700
Qualification of reader**	TS500
Microplate reader IQ/OQ/PQ (document only)	TS550
On-site training**	TS400
Microplate stand	M1000
Marking template for 96-well plate	M1100
Travel expenses	TS2000

*Includes one year extended warranty, spare parts, reader replacement, annual qualification TS500, software upgrades and travel expenses.

**Travel expenses applicable.



The Endosafe®
robotic system offers
increased sample
throughput,
improved technician
productivity
and the reduction
of sample retesting
due to operator
variability.



Endosafe® Robotic System

2008

Endosafe® Robotic System

Charles River Laboratories offers two robot packages designed to meet the demands of the LAL laboratory for increased throughput and decreased analyst variability. These versatile systems, the Hamilton STAR® and STARlet® come in different sizes and have a variety of components available to meet our customers' testing needs. The standard package is a semi-automated system that includes a Hamilton STAR® or STARlet® sample processor with templates customized by Charles River according to customers' SOPs.

The second package is a completely automated robotic system designed specifically for the LAL assay. This package includes the Hamilton STAR® or STARlet® automated robotic system with custom scripts, a robotic arm, and fully integrated endotoxin measuring software for a totally automated LAL robotic system. The Hamilton technology platform for robotic liquid handling has been designed to meet customers' needs for flexibility and expansion.

Advantages of Endosafe® Robotic System

- Increased sample throughput
- Reduced assay variability
- Air-based pipetting technology
- Simple to use with validated, icon-based Vector scripts
- Two worktable sizes for customized throughput
- Advanced liquid handling technology for increased walk-away time
- Versatile system with a variety of robotic arms available with flexible configurations
- Field-upgradeable hardware allowing for expansion as needed
- Fully automated process control with monitoring of liquid aspiration and dispensing.
- Available with a 3-year warranty
- Full IQ/OQ documentation
- 21 CFR Part 11 compliant software on a Windows XP™ platform

Robotic System

	Code
Automated robotic system with custom scripts Hamilton platform 1m deck size- STARlet® or 1.5 m deck size - STAR®	MG200
Automated robotic system package Hamilton automated robotic system with custom scripts Robotic arm with gripper Arm with 4 or 8 pipette tip heads Bar code reader with expanded deck Bio-Tek® plate reader EndoScan-V™ and Vector software package Accessories: Stand, operator safety screen Installation and training	MG400



Charles River's technical staff is committed to provide all our customers superior technical support and consistent customer service throughout the testing process.

CONTRACT TESTING SERVICES

Charles River's technical services laboratory offers comprehensive testing and support services to help improve the compliance and efficiency of your endotoxin detection program. Contract testing services are offered for both gel-clot and kinetic methods. Product development tools such as rapid PTS™ testing and In Vitro Pyrogen Testing (IPT) are also available. For sample submission forms, please send an email to frservtechendo@eu.crl.com

Methods Development

	Code
Methods development	TS100

Routine Endotoxin Determination

	Code
Routine endotoxin determination, any method* PTS™ Gel-clot Kinetic chromogenic Kinetic turbidimetric	TS700

*Test for interfering factors on at least 1 lot must be completed prior to TS700.

In Vitro Pyrogen Test

	Code
Routine pyrogen test by the In Vitro Pyrogen Test (IPT) method	TS702

Gel-Clot Technique

	Code
Test for interfering factors on 3 lots	TS850
Test for interfering factors on 1 lot	TS900
Bacterial Endotoxins Test*	TS950

*Test for interfering factors on at least 1 lot must be completed prior to TS950.

Kinetic Chromogenic Technique

	Code
Test for interfering factors on 3 lots	TS1100
Test for interfering factors on 1 lot	TS1200
Bacterial Endotoxins Test*	TS1300

*Test for interfering factors on at least 1 lot must be completed prior to TS1300.

Kinetic Turbidimetric Technique

	Code
Test for interfering factors on 3 lots	TS1400
Test for interfering factors on 1 lot	TS1500
Bacterial Endotoxins Test*	TS1600

*Test for interfering factors on at least 1 lot must be completed prior to TS1600.

PTS™ Technique

	Code
Test for interfering factors on 3 lots	TS3500
Test for interfering factors on 1 lot	TS3600
Bacterial Endotoxins Test*	TS3700

*Test for interfering factors on at least 1 lot must be completed prior to TS3700.



Contract Testing Services

2008



Charles River Laboratories has grown by understanding the challenges our customers face and developing innovative products that improve the quality of testing.



Contract Testing Services

2008

Stability Test

	Code
Stability Test*	TBET1

*Test for interfering factors on at least 1 lot must be completed prior to TBET1.

Sample Preparation

	Code
Device extraction preparation or special sample preparation such as heat treatment	TS700E

Depyrogenation Validation

	Code
Fixed Cost for depyrogenation validation for vials = 10 ml or below for vials > 10ml	TS1700
Depyrogenation validation Bacterial endotoxins test by the kinetic chromogenic technique <i>*Price on request If PPC are required)</i>	TS1800
Depyrogenation validation Device contamination	TS1900

Additional Services

	Code
Special COA testing	TCOA1
On-site training*	TS400
On-site seminars*	TS400
SOP and protocol writing	TS800

*Travel expenses applicable.

Proficiency Testing Program


The European PTP program is offered four times a year to provide an assessment of lab analysts' proficiency with LAL testing. The program is in place in more than 250 European laboratories. New this year, we are offering a web-based PTP program that will allow users to access their test results and compare their performance directly on-line in a secure web portal.

The dates of the program are:

- Study A08 February 2008 (week 8)
- Study B08 April 2008 (week 18)
- Study C08 June 2008 (week 25)
- Study D08 October 2008 (week 42)

Proficiency Testing Program

	Code
One Study	TPTP
2 Studies	TPTP
3 Studies	TPTP
4 Studies	TPTP
Each additional sample	TPTPX



Blood from the Atlantic horseshoe crab is used to manufacture LAL which is exquisitely sensitive for detecting endotoxin.



IN VITRO PYROGEN TEST

The Endosafe®-IPT is an in vitro pyrogen test that accurately predicts the human response to pyrogens including endotoxins, yeasts, viruses, parasites, and other fever-causing agents. A three-year study by the European Centre for the Validation of Alternative Methods (ECVAM) has evaluated the IPT as an alternative to the rabbit pyrogen test. The IPT works by accurately predicting human response to pyrogens on the more relevant basis of human fever rather than animal models.

Endosafe®-IPT

The *In Vitro* Pyrogen Test (IPT) is an ELISA assay that utilizes human whole blood. Immune cells within the blood will recognize exogenous pyrogen and in response, release fever-inducing signal molecules that can then be measured.

IPT Product Uses

- Complex biologics
- Blood products
- Cellular therapies
- Medical devices
- Environmental air pollutants

Advantages of IPT

- Accurate pyrogen testing in relevant species (human - human)
- Assay replicates testing in physiological environment
- Broad spectrum of pyrogens detected - not only LPS
- High sensitivity
- Low variability between donors
- Simple incubation steps
- Effective test method that replaces animal testing

Endosafe®-IPT

	Code
IPT kit	IPT100
96-well plate with cover	
Secondary antibody	
11 mL TMB	
3 x 30 mL pyrogen-free saline	
Endotoxin control and diluent	
Non-endotoxin pyrogen control	
100 mL wash buffer concentrate	
11 mL STOP solution	



The Endosafe®-IPT is an advancement over the traditional rabbit pyrogen test which is limited by species variations and the absence of standardized controls.

In Vitro Pyrogen Test

2008



Our manufacturing staff, technical and customer services groups, field technical specialists, and sales representatives work diligently to support our customers.

General Terms & Conditions of Sale

A. DELIVERY, ACCEPTANCE AND RISK OF LOSS: Charles River agrees to use commercially reasonable efforts to have the Products available for delivery Carriage and Insurance Paid to Purchaser at the Facility on or before the day which is ninety (90) days from the day on which Charles River receives this Agreement signed on behalf of Purchaser. Charles River assumes no liability, consequential or otherwise, for any delay in or failure to deliver the Products for any reason. Charles River shall notify Purchaser at least ten (10) days prior to the anticipated date the Products are ready for shipment. Charles River shall provide the serial number of each Product before the Delivery Date. Purchaser shall pay Charles River, in addition to the Purchase price, fees for shipping and insurance of the Products. Such amount shall be due within thirty (30) days of the Delivery Date. Purchaser shall be deemed to have finally accepted the Products within two (2) days of the Delivery Date unless Purchaser objects in writing prior to the expiration of such two (2) day period. Risk of loss or damage to the Products shall transfer from Charles River to Purchaser once the Products leave Charles River's facility, and thereafter Purchaser shall not be released from any obligations under this Agreement by reason of any loss of or damage to the Products. Title to the Products shall transfer to Purchaser once Charles River has been paid in full.

B. TRAINING AND INSTALLATION: After Purchaser's acceptance (or deemed acceptance) of the Products, Charles River shall provide training to technicians at the Facility regarding operation of the Products at a time reasonably acceptable to Purchaser and Charles River. Purchaser shall reimburse Charles River for the actual out-of-pocket expenses (travel, hotel and meals) incurred by such technician in travelling to and from the Facility to provide such services.

C. WARRANTY, DISCLAIMERS AND LIMITATIONS OF LIABILITY

(1) Subject to Sections C(2) and C(3) below, the Products will perform in design and manufacture and in conformance with the specifications for a period of one (1) year following the Delivery Date (the "Warranty Period") and the Software (as defined below) used in the operation of the Products will function appropriately within the parameters set forth in the specifications for the Warranty Period.

(2) Purchaser shall notify Charles River promptly of any claims it wishes to make pursuant to the warranty provisions in this Section C. Charles River's sole responsibility under the warranty will be, at its option, either to repair or replace any component that proves defective during the Warranty Period. All defective hardware or parts that are removed and replaced by Charles River will become Charles River's property. To the extent practicable, the warranty service will be performed at the Facility, but may be performed at Charles River's facility if deemed necessary by Charles River in its sole discretion. For the repair or replacement of Products or components under warranty, Purchaser will pay the cost of transportation to Charles River and Charles River will pay the cost of return transportation to Purchaser.

(3) The warranty shall not extend to damage or defects caused by vandalism, shipping, liquid spillage, Acts of God, acts of war, terrorism or other hostilities, any abuse or improper use of the Products or the Software by Purchaser or any third party, servicing or modification of Products and/or Software by persons other than personnel of Charles River or its contractors and/or operation of the Products and/or software outside the environment and operational parameters specified for the Products. The warranty does not apply to Products or components from which any serial numbers or Product registration control numbers have been removed.

(4) The express warranty stated in Section C(1) is in place of all other warranties and conditions, expressed or implied, with respect to the Products, the Software and the Licensed Patents (as defined below), including, but not limited to, implied warranties or warranties of merchantability, fitness for a particular purpose, title and those arising by statute (including latent defect warranties under any commercial code) or otherwise in law or from a course of dealing or use of trade, and Charles River makes no warranties whatsoever regarding non-infringement of third party intellectual property rights. No other warranties apply to the Products.

(5) Except as provided in Section C(7), the maximum liability of Charles River for any cause whatsoever will be limited to the Purchase Price actually paid to Charles River by Purchaser hereunder. In no event will Charles River be liable for any damages resulting from loss of data or use, lost profits or any indirect, incidental, special, consequential or punitive damages. The limitations in this Section C(5) will apply regardless of the form of action, whether for personal injury or physical property damage, under statute, in contract (including fundamental breach), tort, or any other form of action. For the purposes of this Section C(5), "Charles River" includes its directors, officers, shareholders, subsidiaries and affiliates, employees, agents, subcontractors and suppliers.

(6) Subject to the limitations set forth in Section C(5), Charles River shall indemnify and hold harmless Purchaser, its parent and subsidiary companies, and its and their respective directors, employees, subcontractors and suppliers ("Indemnified Persons") from and against any and all claims, damages, liabilities, fines and expenses, including, without limitation, court costs and reasonable attorneys' fees, directly caused by any willful or reckless act or omission of, Charles River or its employees, agents or contractors.

D. DEFAULT: Purchaser shall be deemed in default under this Agreement upon the occurrence of any one of the following: (1) failure of Purchaser to make any payment within five (5) days of its due date, (2) failure to perform any other obligation under this Agreement within thirty (30) days after receipt of written notice of such failure; (3) any representation or statement made or furnished to Charles River by Purchaser in any financial or credit statement or application for credit made prior to this Agreement, proves to have been false in any material respect when made or furnished; (4) loss, theft, destruction, seizure, attachment or unauthorized sale or encumbrance of any of the Products before Charles River has received the Purchase Price in full; or (5) dissolution, insolvency, appointment of a receiver for, commencement of any proceeding under any bankruptcy or insolvency laws by or against Purchaser. In the event of default, Charles River may, at its option and without demand or notice prior to Purchaser, declare all amounts unpaid under this Agreement immediately due and payable and interest shall accrue on the outstanding principal and interest balance at a rate of 1.5% per month, which is 18% percent per annum, or, if lower, the highest interest rate allowed under applicable law, until paid in full, and Charles River shall be entitled to charge a late fee equal to five percent (5%) of any delinquent amounts and to recover attorneys fees and any other costs of collection. If and to the extent applicable Charles River shall have all rights and remedies afforded a secured party pursuant to the provisions of Article 9 of the Uniform Commercial Code or comparable commercial code of the jurisdiction where the Facility is located. No waiver by Charles River, its successors or assigns, of any default including but not limited to acceptance of late payment after the same is due, shall operate as a waiver of any other default or of the same default on a future occasion. Charles River's choice of one remedy does not preclude its election of other remedies.

E. MODIFICATION, ASSIGNMENT: This Agreement shall not be modified except in writing, signed by both parties. Purchaser shall not assign, transfer, pledge, hypothecate or otherwise dispose of this Agreement, or any interest herein, nor shall Purchaser sublet, lend or permit the Products to be used by

anyone other than Purchaser without the prior written consent of Charles River. Charles River may assign any or all of its rights under this Agreement, and Purchaser shall not assert against any such assignee any defence, counterclaim or offset that Purchaser may have against Charles River. Subject to the foregoing, this Agreement shall inure to the benefit of and is binding upon the heirs, legatees, personal representatives, successors and assigns of the parties hereto.

F. REGULATIONS: Purchaser covenants that it will comply with all applicable foreign, federal, state and local laws and regulations with respect to the use and operation of the Products.

G. PURCHASER INDEMNITY: Purchaser agrees that in no event shall Charles River be liable in any way for Customer's use of the Products. Purchaser agrees to indemnify, defend and hold harmless Charles River, its parent and subsidiary and affiliate companies, and its and their respective directors, employees, subcontractors and suppliers from and against any and all claims, damages, liabilities, fines and expenses, including, without limitation, court costs and reasonable attorneys' fees arising from (i) any claim based on Purchaser's use of the Products and/or products or services derived therefrom, or (ii) any breach of Purchaser's obligations hereunder.

H. TAXES AND CUSTOMS: All existing and future sales, use, revenue, excise, VAT or other taxes, duties, fees or charges applicable to the sale, ownership, importing, exporting or use of the Products are the sole responsibility of, and shall be paid by Purchaser. Purchaser shall satisfy all custom formalities.

I. ENTIRE AGREEMENT: This Agreement supersedes any and all prior, contemporaneous or subsequent understandings, proposals, writings, oral representations, or other prior communications between the parties. Purchaser acknowledges that all blanks in this Agreement were complete prior to signing. The terms and conditions stated herein shall prevail over any conflict in terms and conditions between any purchase order submitted by Purchaser and the terms and conditions stated therein.

J. NOTICES: Any notice shall be deemed given under this Agreement upon the date of delivery or two (2) business days after deposit in the mail, registered or certified, postage prepaid, and addressed to Charles River (with a copy to Charles River, 251 Ballardvale Street, Wilmington, MA 01887 Attention: General Counsel) or Purchaser at the address provided in this Agreement.

K. LICENSE; INTERNAL USE RESTRICTION: The software and hardware (collectively "Software") of the Products are provided pursuant to a non-exclusive, non-transferable and non-sublicenseable limited use license permitting use solely by Purchaser. The license shall terminate automatically if Purchaser, or any successor or permitted assignee of Purchaser, (1) ceases doing business, (2) changes its business such that the Products are no longer being utilized in the same manner, or (3) breaches any of the terms of this Agreement. Purchaser shall not, and shall not permit others to copy, modify, reverse engineer, disassemble or decompile the Software, or otherwise reduce the Software to human perceivable form or disclose such software to any third party. Purchaser acknowledges and agrees that Charles River, and/or its licensees, own all right, title and interest in the Software, including the intellectual property rights therein. Nothing herein shall transfer or convey to Purchaser or any other person any right, title or interest in or to any of the intellectual property rights of Charles River in the Software or the Products. The Products and Software are the proprietary and the intellectual property rights of Charles River and Purchaser may be held legally responsible for any patent and copyright infringement or other violation of Charles River's rights that is caused or encouraged by a failure to abide by the terms of this Agreement. The Products may only be used by the Purchaser for internal use only and may not be resold or transferred to another party for any reason.

L. WAIVER OF SOVEREIGN IMMUNITY: To the extent applicable, Purchaser waives its sovereign immunity for the limited purpose of allowing Charles River to enforce its rights under this Agreement.

M. GOVERNING LAW AND CONVENTION ON CONTRACTS FOR THE INTERNATIONAL SALE OF GOODS: This Agreement shall be governed by the laws of the Commonwealth of Massachusetts, USA. The parties specifically exclude the application of the United Nations Convention on Contracts for the International Sale of Goods and any applicable conflict of laws rules imposed thereby. The parties agree that any and all disputes arising under this Agreement shall be heard in the courts of the Commonwealth of Massachusetts, USA.

N. RETURN GOODS: No return can be done without our written approval. Goods must be returned to CHARLES RIVER LABORATORIES France only, BP 109 69592 L'ARBRESLE CEDEX, using the original packaging, and cannot have been modified or changed. The customer will pay the shipping charge. The return will be accepted only after checking by CHARLES RIVER LABORATORIES France of the condition of the goods and packaging. The buyer account will be credited with the corresponding amount 20% or a minimum of £33, for checking the goods will be deducted from the value of the goods

O. PRICES: Prices on our price list are our basic prices for a delivery in metropolitan France. They are granted without any commitment and supplied for information only. For overseas and foreign countries, please contact us. They are established at the beginning of the year, free of tax, net, ex works Sairt Germain sur l'Arbresle, for every delivery in United Kingdom fixed shipping charge of £22. TVA excluded Goods are delivered to the ground floor of the customer premises. Our products will be invoiced at the regular price on the day of the delivery. Installation of equipment is not included in the price.

P. SEVERABILITY : If any provision of this Agreement shall be unlawful, void, or for any reason unenforceable, then that provision shall be deemed severable from the other provisions and shall not affect the validity and enforceability of any remaining provisions. In such event, the invalid provision shall be replaced by a valid provision the Parties would have agreed upon in order to reach the same economic success.

CHARLES RIVER, CHARLES RIVER LABORATORIES, ENDOSAFE, ENDOSCAN-V, ENDOCHROME-K and PTS are trademarks or registered trademarks of Charles River Laboratories, Inc. EPPENDORF® is a registered trademark of Brinkman. TECAN™ is a trademark of Tecan Group AG. EXCEL™ is a trademark of Microsoft Corporation. SEIKO® is a registered trademark of Seiko Kabushiki Kaisha TA Seiko Corporation. Bio-Tek® is a registered trademark of Bio-Tek Instruments, Inc. Epson® is a registered trademark of Seiko Epson Corporation. STAR® and STARlet® are registered trademarks of Hamilton Company. With regard to the Endosafe®-PTS™ products, U.S. Design Patent No. D472,324 and other patents pending.



General Terms & Conditions of Sale

2008



With a clear focus on scientific innovation, excellence, and integrity, Charles River is working to build a partnership with customers based on the highest standards of quality and trust.

Product Index

96-well plates	21
BCA™ cartridge	11
Bio-Tek® microplate reader	25
Borosilicate dilution tubes	19
Contract testing services	29
Control Standard Endotoxin (CSE)	17
Endochrome-K™	13
EndoScan-V™	23
Endotoxin determination test	29
Endotoxin Indicators	17
Endotoxin-free test tubes	19
Endotoxin-specific buffer	17
End-point chromogenic LAL	15
Eppendorf® pipette tips	21
Epson® printer	7
EVV	17
Gel-clot LAL	15
Glass pipettes	21
Gram-ID	9
In Vitro Pyrogen Test (IPT)	33
Incubating microplate reader	25
IPT testing	31
Kinetic chromogenic LAL	13
Kinetic software	23
Kinetic turbidimetric LAL	13
KTA / KTA²	13
LAL buffers	17
LAL Reagent Water (LRW)	17
Marking template	25
Methods development	29
Microplate stand	25
Microtrend	23
Mini pipettor	7
Plate reader	25
Polystyrene plate TCT	21
Portable Test Systems	3
Positive product controls	17
Product release on sample	29
Product validation	29
PTS™ calibration	5
PTS™ cartridge	7
PTS™ extended warranty	5
PTS™ inhibition / enhancement cartridge	7
PTS™ IQ/OQ/PQ	5
PTS™ sample testing	29
PTS™ BCA™	11
PTS™ Gram ID	9
QC-Pac 2 calibration system	25
Qualification of reader/software	25
Robotic system	27
Seiko® printer	7
Soda glass tubes	19
SOP and protocol writing	31
Stability testing on sample	31
Tecan™ microplate reader	25
Tris buffer	17

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Product Index

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