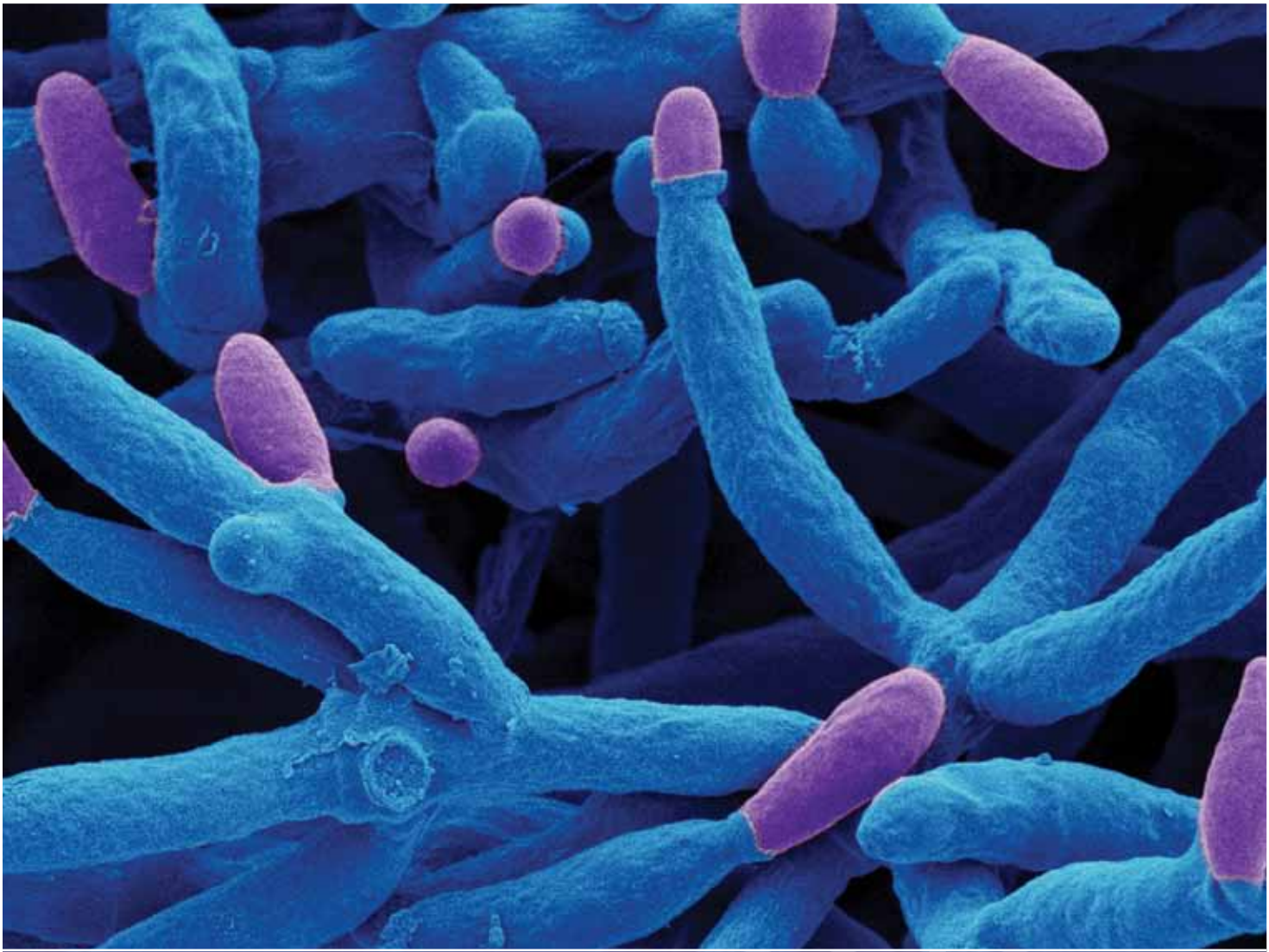
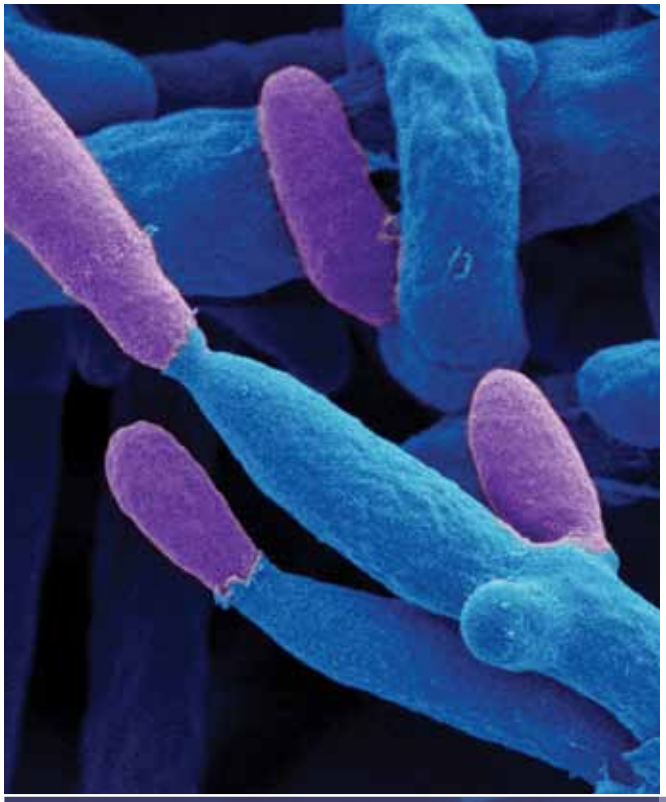


charles river

2013

Endotoxin and Microbial Detection



This year, Charles River introduces new products and services that collectively provide an adaptable, comprehensive QC program for our clients. We have joined forces with Accugenix® (p. 27), an industry leader in FDA-registered, cGMP-compliant contract microbial testing.

Accugenix® has tested and identified more microorganisms than any other company by maintaining a growing proprietary database of over 6,000 microbial profiles.

charles river

2013

Endotoxin and Microbial Detection

We continue to expand our endotoxin testing portfolio with the introduction of the Endosafe® Nexus™ (p. 8). Testing 48 to 60 samples per run, the Nexus™ is the first fully automated robotic system designed for endotoxin testing in the central QC lab.

By expanding our scope of detection and ramping up testing efficiency, Charles River is confident that our new catalog of QC solutions will ensure safety in manufacturing today while preparing us for the challenges of tomorrow.

Table of Contents

charles river | endotoxin and microbial detection

Front cover/inside front (top): *Fusarium incarnatum* is an endophytic fungal plant pathogen of the mangrove plant.

Rapid Testing Systems

Endotoxin testing is a critical checkpoint within the pharmaceutical industry, in areas from dialysis water management to final lot release. However, traditional testing methods have historically caused unnecessary delays because reliable results could not be quickly and easily obtained. Avoid drug delivery limbo with our single-step, rapid testing systems. Simply load your sample into the disposable cartridge and within minutes, get the results you need to move forward with confidence. Training and maintenance support is provided.

PTS™

The PTS™ uses FDA-licensed cartridge technology to provide rapid endotoxin testing at the point of sample collection.

MCS™

The MCS™ is a multi-cartridge endotoxin detection system that tests up to five samples simultaneously.

EndoScan-V™

Both the PTS™ and MCS™ systems use our EndoScan-V™ endotoxin-measuring software, which performs all of the necessary LAL testing calculations.

Nexus™

The Nexus™ is our new multi-cartridge robotic system. This system integrates the Lab of Tomorrow concept by automating, scheduling, sampling, reporting and trending.

PTS™ Glucan Assay

The Glucan Assay quantifies glucans for improved process monitoring and assists in expediting out-of-specification (OOS) investigations.

PTS™ Gram ID

The Gram ID informs the user whether an isolate is a Gram negative or positive bacteria, or confirms yeast or mold, in about three minutes.

The Endosafe®-PTS™

The Endosafe®-PTS™ produces quantitative endotoxin results in approximately 15 minutes. A 15-minute endotoxin assay means fewer bottlenecks and less downtime, improved sample management, and faster production of product. Please see page 6 for information on how to order disposable cartridges for the PTS™.

Endosafe®-PTS™*	Code
Endosafe®-PTS™ instrument	PTS100
Integrated software	
Power supply	
Adaptor cord	
Mini-pipettor	
Operator manual	
Endosafe®-PTS™ package	PTS550
Power supply	
Adaptor cord	
Mini-pipettor	
Operator manual	
Four-year extended warranty	
Printer	
IQ/OQ/PQ	
Endosafe®-PTS™ with EndoScan-V™ software	PTS650
PTS™ instrument and integrated software	
EndoScan-V™ software	
Power supply	
Adaptor cord	
Mini-pipettor	
Operator manual	
Four-year extended warranty	
IQ/OQ/PQ	

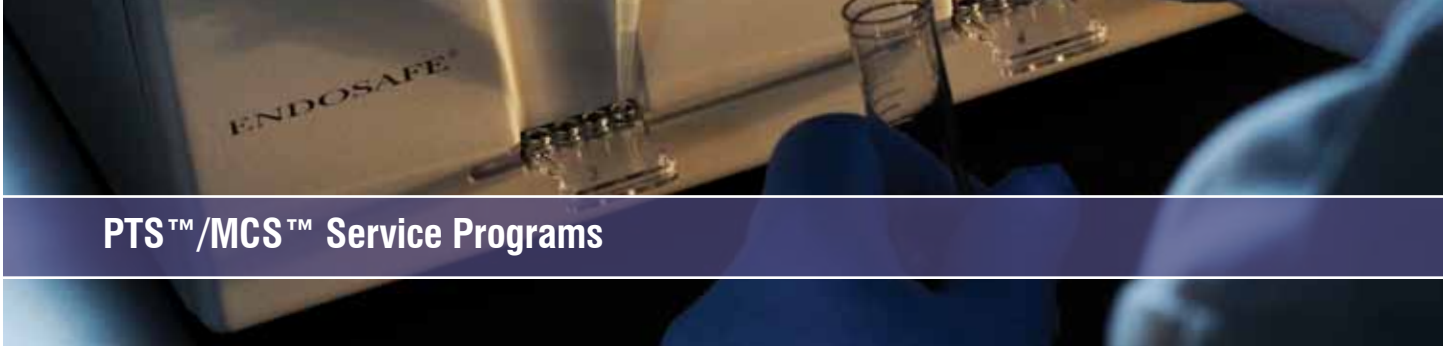
**freight additional*

The Endosafe®-MCS™

The Endosafe®-MCS™ enables you to test up to five samples simultaneously. The MCS™ uses our FDA-licensed disposable LAL cartridges to provide endotoxin determinations in 15 minutes. The system allows random access of samples so you can run them as needed, rather than wait for a full batch. This greatly reduces downtime and improves overall efficiency. The MCS™ also links to the EndoScan-V™ and Microtrend software for sample tracking and trending.

Endosafe®-MCS™*	Code
Endosafe®-MCS™ reader	MCS100
Power supply	
Operator manual	
Endosafe®-MCS™ package	MCS550
MCS™ reader	
EndoScan-V™ software	
Power supply	
Operator manual	
IQ/OQ/PQ	
EndoScan-V™ endotoxin measuring software	M1200

**freight additional*



PTS™/MCS™ Service Programs

Charles River assists in the service and maintenance of your systems and instruments by providing a range of programs for your rapid testing systems.

Endosafe®-PTS™ Service Programs	Code
Annual calibration certification*	PTS500
Four-year extended warranty*	PTS501
PTS™ IQ/OQ/PQ qualification	PTS502
PTS™ IQ/OQ/PQ on site	PTS502S
On-demand repairs	PTS503
On-site calibration	PTS505
Each additional on-site unit for calibration	PTS506
PTS™ rental (one month)	MF100

**Freight additional*
†The four-year extended warranty covers parts and labor and must be purchased within 12 months of initial purchase of instruments.
NOTE: The maximum total warranty period including regional warranty obligations cannot exceed 5 years.

Endosafe®-MCS™ Service Programs	Code
Four-year extended warranty*†	MCS501
MCS™ IQ/OQ/PQ qualification*	MCS502
On-demand repairs	MCS503
MCS™ Annual Qualification Service	MCS500
MCS™ rental (one month)	MF100

**Freight additional*
†The four-year extended warranty covers parts and labor and must be purchased within 12 months of initial purchase of instruments.
NOTE: The maximum total warranty period including regional warranty obligations cannot exceed 5 years.

PTS™/MCS™ Calibration Tools	Code
Portable calibration system*	PTS811

**Pending availability*

PTS™/MCS™ Cartridges

All of our rapid testing instruments utilize our FDA-licensed cartridges for batch release testing, as well as a variety of non-regulated cartridges, for simple, 15-minute testing. MCS™ high-volume users can purchase special licensed multi-pack cartridges for improved efficiency and economy.

Endosafe®-PTS™ Cartridges	Sensitivity EU/mL	Code
10 single packs of cartridges*	0.1	PTS201F
	0.05	PTS2005F
	0.01	PTS2001F
	0.005	PTS20005F

**Licensed by the FDA*

Endosafe®-PTS™ Cartridges	Sensitivity EU/mL	Code
10 single packs of cartridges (unlicensed)	0.1	PTS201
	0.05	PTS2005
	0.01	PTS2001

Endosafe®-PTS™ Cartridges	Sensitivity EU/mL	Code
Multi-packs of 25 cartridges (5/pouch)*	0.1	PTS551F
	0.05	PTS5505F
	0.01	PTS5501F
	0.005	PTS55005F

The cartridges must be used within two hours of breaking the pouches seal.
**Licensed by the FDA*

Inhibition/Enhancement Screening Cartridges†	Code
10 single packs of cartridges†	PTS220

†Inhibition/Enhancement Screening Cartridges are not licensed by the FDA.

PTS™/MCS™ Accessory Products

From calibration tools with temperature and optical devices, to printers and protective cases, our rapid testing instruments come with a wide range of accessories.

PTS™/MCS™ Accessories	Code
PC to PTS™ cable	PTS108
AC power supply	PTS109
USB to serial converter	PTS111
Seiko® thermal printer	PTS300
Thermal paper for Seiko® printer	PTS301
Seiko® printer cable	PTS302
Epson® dot matrix printer	PTS310
Epson® printer cable	PTS311
Ribbon for Epson® printer	PTS312
Paper roll for Epson® printer	PTS313
Continuous roll label for Epson® printer	PTS314
Mini-pipettor (25 µL, disposable)	PTS400
Protective reader case	PTS600
Eppendorf® 25 µL pipettor	PTS700
Gilson® 25 µL pipettor	PTS700
PTS™ blank cartridges	PTS200

Endosafe® Nexus™

The Nexus™ (Multi-Cartridge Robotic System) has been developed to eliminate technician variability, further reducing retests and the need for costly investigations. The technician simply loads the bar-coded samples on the robotic deck and walks away. The system will make dilutions, add samples to the cartridge, and place the cartridge in the MCS™. The 5 MCS™ cartridge slots operate independently, with full random access, meaning samples can be tested with the minimum of technician time. Results can be tracked and trended via EndoScan-V™ and Microtrend.

Combining the MCS™ with a robotic system brings advantages over robotics utilizing microplates, with greater flexibility eliminating the need to modify robotic software templates and scripts.

The Nexus™ delivers error-free, high throughput LAL testing in a low maintenance, flexible, high-precision package.

Endosafe® Nexus™*	Code
Endosafe® Nexus™ robotic system Nexus™ robotic system MCS™ reader EndoScan-V™ software Computer Nexus™ accessory kit IQ/OQ/PQ	MR650

**Freight additional*

Endosafe® Nexus™*	Code
Endosafe® Nexus™ robotic system	MR550
Nexus™ robotic system	
Nexus™ accessory kit	
Computer	
IQ/OQ/PQ	

**Freight additional*

Endosafe® Nexus™ Service Programs*	Code
Nexus™ annual service	MR500
Nexus™ IQ/OQ/PQ	MR502

**Freight additional*

Endosafe®-PTS™ Glucan Assay

The PTS™ Glucan Assay quantifies glucans, leading to better process monitoring and faster out-of-specification resolutions. The disposable glucan cartridges have a sensitivity range of 10-1,000 pg/mL and produce results in less than 30 minutes.

Endosafe®-PTS™ Glucan Assay	Code
Endosafe®-PTS™ instrument	PTS100
Integrated software	
Power supply	
Adaptor cord	
Mini-pipettor	
Operator manual	
Four-year extended warranty†	PTS501
Epson® printer	PTS310
EndoScan-V™ endotoxin-measuring software	M1200

**Freight additional*
†The four-year extended warranty covers parts and labor and must be purchased within 12 months of initial purchase of instruments.
NOTE: The maximum total warranty period including regional warranty obligations cannot exceed 5 years.

Endosafe®-PTS™ Glucan Cartridges	Code
Glucan cartridges	RMMGS1000

Endosafe®-PTS™ Gram ID

The PTS™ Gram ID is a fast, simple, one-step process test that measures differences in the cell walls of microbial isolates. With four samples per cartridge, this stain-free assay provides a determination of Gram positive or negative results in about three minutes, thereby eliminating technician variability.

Endosafe®-PTS™ Gram ID	Code
Endosafe®-PTS™ instrument	PTS100
Integrated software	
Power supply	
Adaptor cord	
Mini-pipettor	
Operator manual	
Four-year extended warranty†	PTS501
Epson® printer	PTS310
EndoScan-V™ endotoxin-measuring software	M1200

**Freight additional*
†The four-year extended warranty covers parts and labor and must be purchased within 12 months of initial purchase of instruments.
NOTE: The maximum total warranty period including regional warranty obligations cannot exceed 5 years.

Endosafe®-PTS™ Gram ID Cartridges	Code
Gram ID cartridges	GI100

Kinetic Turbidimetric LAL

Our FDA-licensed kinetic turbidimetric reagents yield quantitative endotoxin values when used with a microplate equipped with endotoxin-measuring software. KTA is licensed for both kinetic and gel-clot analyses and permits a direct correlation between methods. KTA^2 is a second-generation kinetic turbidimetric reagent only. It offers faster reaction times and routinely tests to sensitivities of 0.005 EU/mL.

Kinetic Turbidimetric LAL† 50-Test Vial (5.2 mL)	Sensitivity EU/mL	Code
KTA^2	*	R19000
KTA	*	R15015
	*	R15003
	*	R15006

†Reserves of LAL reagents and matching CSE are offered for a period of one year.
**Routinely run on 50-0.005 EU/mL but can run to 0.001 EU/mL with appropriate instrument and consumable(s).*

Chromogenic LAL

Endochrome-K™ LAL facilitates your endotoxin screening with its ease of use and unique reagent stability. Our optimized kinetic chromogenic (KCA) LAL offers a 0.001 EU/mL limit of detection and provides greater linearity and superior interference resistance for quantitative endotoxin values in about an hour.

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	*	R1708K
Endochrome-K™ 320 tests 10 x 3.2 mL vials	*	R1710K
Endochrome-K™ 3200 tests 100 x 3.2 mL vials	*	R17100K

†Reserves of LAL reagents and matching CSE are offered for a period of one year.
**Routinely run on 50-0.005 EU/mL but can run to 0.001 EU/mL with appropriate instrument and consumable(s).*

Endpoint Chromogenic Reagents	Code
Endpoint chromogenic kit (140 tests) 5 x 1.4 mL vials of chromogenic LAL 1 x 10 mg vial of chromogenic substrate S-2423 2 x 2 ng vials of endotoxin 2 x 30 mL vials of LAL reagent water 1 x 15 mL buffer 0.05 M Tris vials	R160

Endosafe® Gel-Clot LAL

The gel-clot assay is a simple, qualitative method. Endosafe® lysate features a firm gel over a wide range of sensitivities. Additionally, the reagent is buffered for enhanced interference resistance.

Gel-Clot LAL 50-Test Vial (5.2 mL)	Sensitivity EU/mL	Code
50-Test vial (5.2 mL)	0.015	R15015
	0.03	R15003
	0.06	R15006
	0.125	R11012
	0.25	R11025

Gel-Clot LAL 10-Test Vial (1.2 mL)	Sensitivity EU/mL	Code
10-Test vial (1.2 mL)	0.03	R12003
	0.06	R12006
	0.125	R12012
	0.25	R12025

Gel-Clot LAL Single-Test Vial (0.2 mL)	Sensitivity EU/mL	Code
Single-test vial (0.2 mL)	0.03	R13003
	0.06	R13006
	0.125	R13012
	0.25	R13025

Rapid Single-Test LAL Vials (0.2mL)*	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.*

LAL Accessory Products

Charles River provides all of the necessary accessory products required to run an LAL test. Our accessory products are all certified for the appropriate LAL testing requirements. These high-quality accessories impart control and consistency to the LAL laboratory, thereby minimizing invalidities and repeat testing.

Control Standard Endotoxin (CSE) *E. coli* and Reference Standard Endotoxin (RSE)	Code
CSE - 500 ng per vial*	E110
CSE - 10 ng per vial*	E120
Positive control (for single test)	PC100
Reference standard endotoxin USP (10,000 EU per vial)	E150
Reference standard endotoxin EU (10,000 IU per vial)	E160

**Lot-specific Certificate of Analysis included*

CXE Kit*	Code
CXE Extended CSE dilution kit 1 x 10 ng CSE 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)*	Code	Package
30 mL bottle (<0.001 EU/mL)	W130	12/case
50 mL bottle (<0.001 EU/mL)	W120	12/case
100 mL bottle (<0.001 EU/mL)	W110	12/case
500 mL bottle (<0.001 EU/mL)	W150	6/pack

**Lot-specific Certificate of Analysis included*

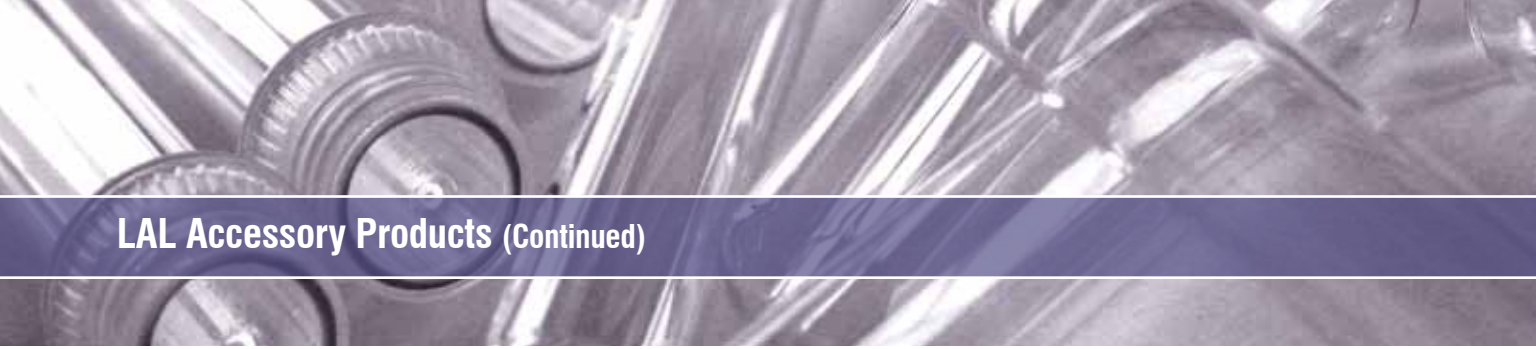
LAL Buffers*	Code	Package
5 mL 0.25 M Tris buffer	BT101	6/pack
30 mL 0.1 M Tris buffer	BT103	12/case
5.5 mL 0.1 M Tris buffer	BT105	6/pack
30 mL 0.05 M Tris buffer	BT106	12/case
4 mL 0.5 M $MgSO_4$, 1 M Tris buffer	BC1000	6/pack
5.2 mL Endotoxin-specific buffer	BG120	6/pack
30 mL Bio-dispersing agent	BD100	12/case

**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*

Validated PETG Bottles for LAL Sampling	Code	Package
30 mL bottles	F1030	24/pack
60 mL bottles	F1060	24/pack
125 mL bottles	F1125	24/pack
250 mL bottles	F1250	24/pack
500 mL bottles	F1500	24/pack
1000 mL bottles	F1000	24/pack
2000 mL bottles	F2000	24/pack



LAL Accessory Products (Continued)

Depyrogenated and Endotoxin-Free Certified Test Tubes

Reaction Tubes	Code	Package
10 x 75 mm capped flint glass tubes in a box	T100	50/pack
10 x 75 mm flint glass tubes wrapped in aluminum foil	T200	50/pack
10 x 75 mm borosilicate glass tubes wrapped in aluminum foil (appropriate for use with tube readers)	T400	50/pack
8 x 75 mm borosilicate glass tubes wrapped in aluminum foil (only for use with tube readers)	T500	50/pack
10 x 75 mm screw cap borosilicate glass tubes in a box	TL1200	50/pack

Dilution Tubes	Code	Package
13 x 100 mm borosilicate glass tubes wrapped in aluminum foil	T300	50/pack
16 x 90 mm screw-cap borosilicate glass tubes in a box	TL700	70/pack
12 x 75 mm borosilicate glass tubes wrapped in aluminum foil	TL1000	50/pack

Sampling Tubes	Code	Package
18 x 150 mm borosilicate glass tubes wrapped in aluminum foil	T600	14/pack
16 x 160 mm screw-cap borosilicate glass tubes in a box	TL800	100/pack
14 mL Falcon™ tubes	TF3000	25/pack
15 mL Falcon™ tubes	TF3100	50/pack

Depyrogenated Glass Pipettes	Code	Package
1 mL wrapped in aluminum foil	P100	5 packs of 10
2 mL wrapped in aluminum foil	P200	5 packs of 10
5 mL wrapped in aluminum foil	P500	5 packs of 10
10 mL wrapped in aluminum foil	P1000	5 packs of 10

Eppendorf® Pipette Tips	Code	Package
Eppendorf® tips (2-200uL, individually wrapped)	D200	100/pack
Eppendorf® tips (50-1000uL, individually wrapped)	D1000	100/pack

Endosafe® Pipette Tips	Code	Package
2-200 µL pipette tips (individually wrapped)	D200IW	400/pack
2-200 µL pipette tips (96-racked)	D200ST	10 racks/pack
100-1000 µL pipette tips (individually wrapped)	D1000IW	400/pack
100-1000 µL pipette tips (96-racked)	D1000ST	10 racks/pack

**Available in Europe*

96-Well Endosafe® Plates (individually wrapped)*	Code	Package
96-well polystyrene plate (certified to 0.005 EU/mL)	M9005	50/box

Validated Reservoir for Mixing Reagent Vials	Code	Package
55 mL reservoirs (individually wrapped)	F80	80/pack

Dispenser Tips	Code	Package
Tips - 0.5 mL (individually wrapped)	PF1600	100/box
Tips - 2.5 mL (individually wrapped)	PF1800	100/box
Tips - 5 mL (individually wrapped)	PF1900	100/box

Proteus NoEndo™ Spin Column Kits

The Proteus kits are designed for simple, rapid removal of endotoxin from a wide range of protein solutions. Proteus spin columns replace lengthy and expensive chromatographic methods such as phase separation and FPLC®. Large numbers of samples can be processed at the same time. Protein samples purified using Proteus spin columns may be used for a wide range of laboratory procedures, such as biopharmaceutical preparations for proteins, antibodies and vaccines.

Proteus NoEndo™ Spin Column Kits	Code	Kit Quantity
Proteus NoEndo*μ* (Micro) 2 column kit	ERE2Micro	2
Proteus NoEndo*μ* (Micro) 24 column kit	ERE24Micro	24
Proteus NoEndoM (Mini) 2 column kit	ERE2M	2
Proteus NoEndoM (Mini) 12 column kit	ER12M	12
Proteus NoEndoS (Standard) 2 column kit	ERE2S	2
Proteus NoEndoS (Standard) 12 column kit	ER12S	12
Proteus NoEndoHC (High Capacity) 2 column kit	ERE2Hc	2
Proteus NoEndoHC (High Capacity) 12 column kit	ERE12HC	12

Proteus kits are configured based on the starting endotoxin load in your sample

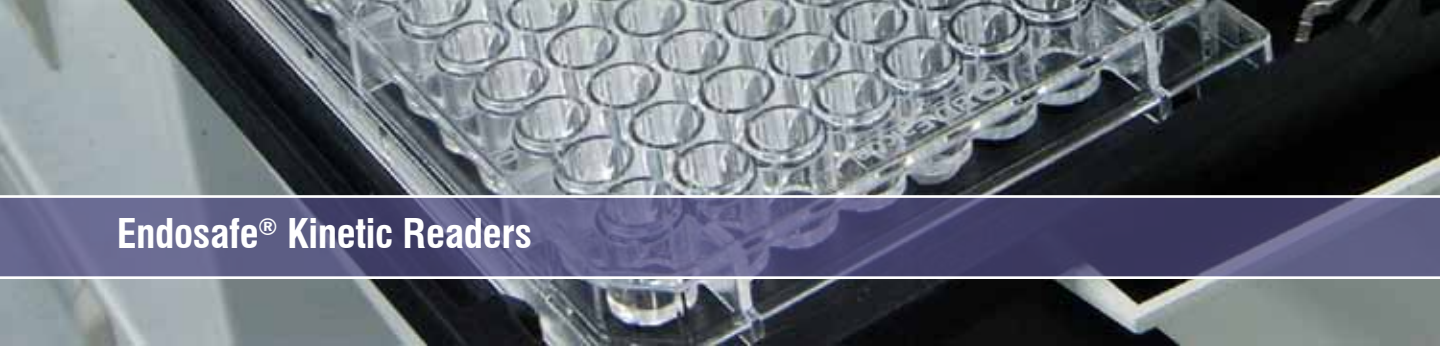
EndoScan-V™ and Microtrend Software

Your kinetic endotoxin detection program requires accurate and intuitive data analysis. Consistent with FDA requirements, EndoScan-V™ performs calculations and creates batch reports for product release. The software's flexible networking configuration improves operational efficiencies overall. And, for added protection, EndoScan-V™ generates secure data files and audit trails on all actions involving files and test data.

The EndoScan-V™ software comes with a comprehensive help section and IQ/OQ/PQ guidelines. The program can be interfaced with trending software, Excel™, LIMS and centralized databases, and is available in English, French and German.

Microtrend is our next-generation, data-trending software that leverages the power of Structured Query Language (SQL) to track and trend LAL test data. This software works with exported files from EndoScan-V™ to analyze and manage LAL test data.

Endosafe® Software	Code
Endosafe® EndoScan-V™ endotoxin-measuring software (compatible with Bio-Tek® plate readers, PTS™ and MCS™)	M1200
EndoScan-V™ software validation package	TS600
Electronic Signature (available early 2013)	M1300
Microtrend database-trending software (compatible with Bio-Tek® plate readers, PTS™ and MCS™)	M804
Microtrend software validation package	TS1000



Endosafe® Kinetic Readers

Our compact, multi-use spectrophotometers offer superior temperature uniformity and excellent optical performance. We also provide technical support for our plate readers, including on-site annual qualification and user training.

Bio-Tek® Kinetic Plate Readers and Accessories	Code
Bio-Tek® incubating microplate reader (with 340, 405, 450, 490, 620 nm filters)	M200
Calibration plate for Bio-Tek® reader	M400
Calibration plate recertification (valid for one year) - Bio-Tek®	TS3000
Bio-Tek® bulb	M700

Plate Reader Options	Code
Service contract for reader†	TS2700
Annual qualification of reader/software*	TS500
Reader service qualification IQ/OQ/PQ	TS502
Microplate reader IQ/OQ/PQ (document only)	TS550
Computer package (computer and monitor)	MF1500
Printer	MF1600
On-site training of reader/software	TS400
Microplate stand	M1000
Marking template for 96-well plate	M1100
Travel expenses	TS2000

**Travel expenses applicable*
†Includes one-year extended warranty, spare parts, reader replacement if available, annual qualification software upgrades and travel expenses

Contract Testing Services

Our technical services laboratory offers a variety of testing and support services, cGMP-compliant work can be performed through our ISO 9001v2008 certified facility-FDA-registered as of December 2009. We also offer results analysis, SOP writing assistance, protocol recommendations and standard or customized LAL training courses. Our COFRAC accredited facility (ISO17025v2005) is approved to perform the Bacterial Endotoxins Test (BET) in accordance with all methods described in the European Pharmacopeia and USP. For sample submission forms, please visit www.criver.com. For technical information, please email us at frservtechendo@crl.com.

Methods Development	Code
Methods development	TS100

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

**Not on ISO 17025 scope*

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

**Product validation must be completed prior to finished product release or stability testing.*

cofrac
ESSAIS
ACCREDITATION
N° 1-1850
Scope Available On
sur www.cofrac.fr

Contract Testing Services (Continued)

Kinetic Chromogenic Technique	Code
Product Validation – 3 lots	TS1100
Product Validation - 1 lots	TS1200
Product release or stability test*	TS1300

**Product validation must be completed prior to finished product release or stability testing.*

Kinetic Turbidimetric Technique	Code
Product Validation – 3 lots	TS1400
Product Validation – 1 lots	TS1500
Product release or stability test*	TS1600

**Product validation must be completed prior to finished product release or stability testing..*

PTS™ Technique	Code
Product Validation – 3 lots	TS3500
Product Validation – 1 lots	TS3600
Product release or stability test*	TS3700

**Product validation must be completed prior to finished product release or stability testing.*

Stability Testing	Code
Stability testing*	TBET1

**Product validation must be completed prior to finished product release or stability testing.*

cofrac
ESSAIS
ACCREDITATION
N ° 1-1850
Scope Available On
sur www.cofrac.fr

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

**If Charles River prepares the extraction or treats the sample, there is an additional price per sample.*

Oven Depyrogenation Validation	Code
Oven validation/testing of challenge vials†	TS1700
for vials = 10mL or below	
for vials > 10mL	
Depyrogenation validation*	TS1800
Bacterial endotoxins test by the kinetic chromogenic assay	
Depyrogenation validation	TS1900
Device contamination†	

**Price on request if PPC is required*
†Not on ISO 17025 scope

cofrac
ESSAIS
ACCREDITATION
N° 1-1850
Scope Available On
sur www.cofrac.fr

Additional Services	Code
Special COA testing	TCOA1
On-site training*	TS400
Protocol writing	TS800

**Travel expenses applicable*

Endosafe® LAL Proficiency Test Program

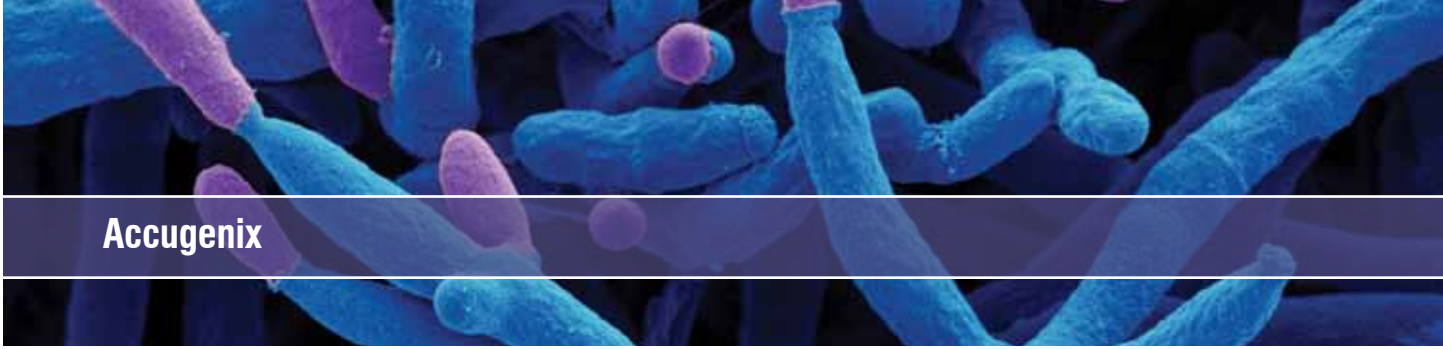
The Charles River Proficiency Test Program (PTP) is a tool for confidential quarterly audits of your LAL analysts. With more than 350 participants worldwide, the Charles River PTP ensures internal quality assurance and helps verify methods, report validations, identify trends and spot possible training needs.

Endosafe® LAL Proficiency Test Program - Procedure

Participating analysts test a blind sample provided by Charles River. After testing, results are submitted through the Charles River web portal: www.lal-ptp.com. Our technicians evaluate submissions and send a report to all audit participants with the detailed results. Start dates for the Proficiency Test Program include: week 7 (February 2013), week 16 (April 2013), week 29 (July 2013), and week 42 (October 2013).

For information regarding the Proficiency Test Program, please email ptp.support@crl.com, or contact us at +33 (0) 474 72 28 53.

Proficiency Testing Program*	Code
1 study	TPTP1
2 studies	TPTP2
3 studies	TPTP3
4 studies	TPTP4
Each additional sample	TPTPX



Accugenix

Accugenix is the newest addition to the Charles River Endotoxin and Microbial Detection portfolio of products and services. Accugenix is an acknowledged industry leader in species-level identification and strain typing of bacteria and fungi that are recovered from manufacturing facilities. Utilizing state-of-the-art and proprietary *in vitro* technologies, coupled with scientific expertise and analysis, Accugenix provides accurate, rapid and cost-effective microbial testing services required to meet global regulatory standards.

By partnering with Accugenix, you will have access to:

- Our validated, relevant bacterial and fungal libraries, which are considered to be the industry's gold standard
- Our proprietary identification services that have an industry-leading 98% reportable rate and an impressive 99% on-time delivery rate
- cGMP-compliant laboratories, validated databases and robust methods to ensure consistent and reproducible results required for EM programs
- A lower cost and higher accuracy per reportable result than in-house testing or comparable contract laboratory service providers using commercial systems

AccuGENX-ID® - Genotypic Identification of Bacteria and Fungi (rDNA Sequencing)

Performance Claims†: Reportable Rate – 98% Error Rate – 0.2%

AccuGENX-ID® genotypic identification methods are the industry's gold standard for the identification of microorganisms. The sequence-based identification techniques for bacteria (16S 500bp) and fungi (ITS2 region) are independent of the health or growth conditions of the isolate; samples can be viable or nonviable cultures or simply genomic DNA from your microbe.

TURNAROUND TIME (TAT)	TEST CODE BACTERIA (16S 500bp)	TEST CODE FUNGI (ITS2)
Same Day	BacSeq-0	FunITS-0
1 Day	BacSeq-1	FunITS-1
2 Days	BacSeq-2	FunITS-2
5 Days	BacSeq-5	FunITS-5
10 Days	BacSeq-10	FunITS-10

†Performance claims are based on internal Accugenix studies on microorganisms commonly found in sterile and aseptic manufacturing environments.

AccuBLAST® - Analysis & Interpretation of 16S or ITS2 Raw Data Sequence Files (*.ab1)

Our AccuBLAST® service is ideal for laboratories that process and sequence their own microbial isolates, but prefer to have their MicroSEQ® data assembled and analyzed according to our semi-automated process. We leverage sophisticated problem-solving methods to help customers reconcile otherwise inaccurate or inconsistent data.

TURNAROUND TIME (TAT)	TEST CODE (16S, ITS2)
Same Day	AccuBLAST-0
1 Day	AccuBLAST-1
2 Days	AccuBLAST-2
5 Days	AccuBLAST-5

AccuPRO-ID® - Proteotypic Identification of Bacteria (MALDI-TOF Backed by 16S Sequencing)

Performance Claims*: Reportable Rate – 98% Error Rate – 2%

AccuPRO-ID® was designed for organizations that need routine bacterial identification, but with greater accuracy and confidence than dated phenotypic methods offer. Numerous case studies have demonstrated a significant improvement of 30-40% in accuracy over existing phenotypic methods. Samples with no result are automatically tested with the AccuGENX-ID® service at no additional cost.

TURNAROUND TIME (TAT)	TEST CODE BACTERIA
Same Day	AccuPRO-ID-0
1 Day	AccuPRO-ID-1
2 Days	AccuPRO-ID-2
5 Days	AccuPRO-ID-5
10 Days	AccuPRO-ID-10

**Performance claims are based on internal Accugenix studies on microorganisms commonly found in sterile and aseptic manufacturing environments.*

Strain Typing – Key for Tracking and Trending

As a complement to our sequence-based microbial identification services, Accugenix offers our AccuGENX-ST™ multi and single locus sequence typing (MLST, SLST) service, as well as automated ribotyping (BacRib) for strain-level characterization and tracking of bacterial isolates. Contact us at askcharlesriver@crl.com to learn more about these services, including pricing, test code and turnaround time information.

Special pricing rates are determined based on historical or anticipated monthly sample volume. Corporate pricing is available for companies with multiple sites to adopt standardized programs for microbial identifications across their worldwide manufacturing and vendor sites. Contact us at askcharlesriver@crl.com to learn more about special pricing opportunities.

Ordering Information

CUSTOMER SERVICE:

toll free: 00.800.15.78.97.43
fax: 00.33.4.74.01.65.31
address: BP 109 - 69592
L'Arbresle Cedex - France

TECHNICAL SALES MANAGERS

United Kingdom and Ireland
email: ukendo@crl.com

UK North and Ireland Jonathan Malkin
phone: +44 7774 640838
e-mail: jonathan.malkin@crl.com

UK Mid + West Nicola Swift
phone: +44 7717 872515
e-mail: nicola.swift@crl.com

UK South + East Matthew Reynolds
phone: +44 7717 872513
e-mail: matthew.reynolds@crl.com

Belgium,The Netherlands, Luxembourg
email: bnxendo@crl.com

Debby Te Wierik
phone: +31 622 042 700
e-mail: debby.tewierik@crl.com

An Velaers
phone: +32 471 79 55 60
e-mail: an.velaers@crl.com

Sweden, Norway, Denmark, Finland
email: scendo@crl.com

Wilhelm Johnsson
phone: +46 705 867 116
e-mail: wilhelm.johnsson@crl.com

Susanne Gröndahl
phone: +46 709 440 086
e-mail: susanne.grondahl@crl.com

Austria, Hungary, Czech Republic and Slovakia
email: deendo@crl.com

Bedrettin Sanac
phone: +43 664 166 15 56
e-mail: bedrettin.sanac@crl.com

Germany
email: deendo@crl.com

Marion Usedom
phone: +49 172 82 64 141
e-mail: marion.usedom@crl.com

West Sascha Bär
phone: +49 172 82 64 400
e-mail: sascha.baer@crl.com

South Dr. Ursula Dörner
phone: +49 172 82 64 408
e-mail: ursula.doerner@crl.com

South West Dr. Dirk Fröde
phone: +49 172 82 64 132
e-mail: dirk.froede@crl.com

North and East Dr. Elena Stangeew
phone: +49 172 82 64 045
e-mail: elena.stangeew@crl.com

Switzerland
German speaking Dr. Dirk Fröde
phone: +49 172 82 64 132
e-mail: dirk.froede@crl.com

French speaking Cedric Bianchi-Amoretti
phone : +33 6 74 73 04 92
e-mail : cedric.bianchi-amoretti@crl.com

Italian speaking Alessandro Pauletto
phone: +39 335 794 19 65
e-mail : alessandro.pauletto@crl.com

France
email : frendo@crl.com

Paris , North Est Constance Desmarre
phone : +33 6 32 55 15 87
e-mail : constance.desmarre@crl.com

Paris, Center and West Yann Puigmal
phone : +33 6 76 12 72 18
e-mail : yann.puigmal@crl.com

South Cedric Bianchi-Amoretti
phone : +33 6 74 73 04 92
e-mail : cedric.bianchi-amoretti@crl.com

Italy
email : itendo@crl.com

North Alessandro Pauletto
phone: +39 335 794 19 65
e-mail : alessandro.pauletto@crl.com

Toscana, Liguria ed Emilia Romagna
Monica Vizzi
phone : +39 335 794 19 64
e-mail : monica.vizzi@crl.com

Center and South Claudia Di Paola
phone: +39 334 655 83 67
e-mail : claudia.dipaola@crl.com

Spain & Portugal
email: esendo@crl.com

Andorra, Aragón, Baleares, Catalunya, La Rioja, Navarra, País Vasco Olga Balaguer
phone: +34 619 46 52 00
e-mail: olga.balaguer@crl.com

Others David Miquel
phone: +34 619 46 52 69
e-mail: david.miquel@crl.com

Algeria, Bahrain, Jordan, Kuwait, Lebanon, Morocco, Oman, Qatar, Saudi Arabia, Tunisai, United Arab Emirates, Yemen
email: eurendoexport@crl.com

Dr. Samia Dabouz
phone: +33 6 64 83 24 56
e-mail: samia.dabouz@crl.com

Croatia, Slovenia, Serbia, Bosnia and Herzegovina, Montenegro, Macedonia, Albania, Bulgaria
email: eurendoexport@crl.com

Dr. Rahela Sopta
phone: +38 591 540 33 80
e-mail: rahela.sopta@crl.com

Any other country
email: eurendoexport@crl.com

PROFICIENCY TESTING PROGRAM

For information regarding the PTP or results.
phone: +33 4 74 72 28 53
fax: +33.4.74.72.28.21
e mail: ptp.support@crl.com

CONTRACT TESTING SERVICES

For sample submission forms and informations.
phone: 00.33.4.74.01.69.32
fax: 00.33.4.74.72.28.21
e mail: frservtechendo@crl.com

ACCUGENIX

Accugenix, EU laboratory
Bat. E2
327 Impasse du Domaine Rozier
Domaine des Oncins
69210 Saint Germain sur l'Arbresle
France

toll free: 00.800.15.78.97.43
fax: 00.33.4.74.01.65.31

Accugenix, Inc.
223 Lake Drive
Newark, DE 19702 USA

phone: +1.302.292.8888
toll free: 800.886.9654
fax: +1.302.292.8468
email: endosafecustomerservice@crl.com

Accugenix® Literature Requests:
accugenix-marketinginfo@crl.com

Accugenix® Technical Support:
accugenix-customersupport@crl.com

Accugenix® Sales Department:
askcharlesriver@crl.com

For a list of worldwide locations or to obtain product literature or technical documentation, please visit our website at: www.criver.com/endosafe.

Product Index & Calculations

Drugs

EL = K/M
K = 5 EU/kg
K = 0.2 EU/kg for intrathecal
M = max dose/kg/hour
MVD = EL/λ
MVC = λ/EL
EL = Endotoxin limit
MVC = Minimum valid concentration
MVD = Maximum valid dilution

Devices

K = Endotoxin limit EU/device
N = Number of devices pooled
V = Total volume used in extraction of pooled devices
Endotoxin limit = 20 EU/device
or
Intrathecal = 2.15 EU/mL
EL = $\frac{K \times N}{V}$ (for extract, not device)

General Terms and Conditions of Sale

General Terms/Conditions of Sale for LAL, PTS™ and Related Products (the "Products") and AccuGENX-ID®, AccuPRO-ID® AccuBLAST® (the "Services")

Any Services (except the training and installation referred to in Section B below) performed by Charles River or Accugenix (the "Company") are subject to the terms and conditions on our website at http://www.criver.com/termsandconditions.

A. DELIVERY, ACCEPTANCE AND RISK OF LOSS: The Company agree to use commercially reasonable efforts to have the Products available for delivery Carriage and Insurance Paid on or before the day which is ninety (90) days from the day on which the Company receives an order signed on behalf of purchaser. The Company assumes no liability, consequential or otherwise, for any delay in or failure to deliver the Products for any reason. The Company shall notify purchaser at least ten (10) days prior to the anticipated date the Products are ready for shipment. If applicable, the Company shall provide the serial number of each Product before the delivery date. Purchaser shall pay the Company, 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 the Company to purchaser once the Products leave Charles River's facility, and thereafter purchaser shall not be released from any obligations by reason of any loss of or damage to the Products. Title to the Products shall transfer to purchaser once the Company has been paid in full.

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

C. WARRANTY, DISCLAIMERS AND LIMITATIONS OF LIABILITY: (1) The Company warrants that the Services provided to Purchaser shall conform to the Company's current testing specifications and with applicable current Good Manufacturing Practices (cGMPs). Any claim for breach of this warranty must be made in writing to the Company within ten (10) days after completion of the Services, after which time the Services shall be deemed finally accepted. (2) Subject to Sections C(3) and C(4) 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. (3) Purchaser shall notify the Company promptly of any claims it wishes to make pursuant to the warranty provisions in this Section C. The Company'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 the Company will become the Company's property. To the extent practicable, the warranty service will be performed at the purchaser's facility, but may be performed at the Company's facility if deemed necessary by the Company in its sole discretion. For the repair or replacement of Products or components under warranty, purchaser will pay the cost of transportation to the Company and the Company will pay the cost of return transportation to purchaser. (4) 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 the Company 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. (5) The express warranty stated in Sections C(1) and C(2) are in place of all other warranties and conditions, expressed or implied, with respect to the Products, Services, Software and 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 the Company makes no warranties whatsoever regarding non-infringement of third party intellectual property rights. No other warranties apply to the Products and Services. (6) Except as provided in Section C(8), the maximum liability of the Company for any cause whatsoever will be limited to the purchase price actually paid to the Company by purchaser hereunder. In no event will the Company 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(6) 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(6), the "Company" includes its directors, officers, shareholders, subsidiaries and affiliates, employees, agents, contractors, subcontractors and suppliers. (7) Subject to the limitations set forth in Section C(6), the Company 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, the Company or its employees, agents or contractors.

D. DEFAULT: Purchaser shall be deemed in default 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 of purchaser within thirty (30) days after receipt of written notice of such failure; (3) any representation or statement made or furnished to the Company by Purchaser in any financial or credit statement or application for credit 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 the Company 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, the Company may, at its option and without prior demand or notice to purchaser, declare all amounts unpaid 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 the Company 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, the Company 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 purchaser's facility is located. No waiver by the Company, 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. The Company's choice of one remedy does not preclude its election of other remedies.

E. MODIFICATION, ASSIGNMENT: Purchaser shall not sublet, lend or permit the Products to be used by anyone other than purchaser without the prior written consent of the Company. The Company may assign any or all of its rights, and purchaser shall not assert against any such assignee any defense, counterclaim or offset that purchaser may have against the Company.

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 the Company be liable in any way for purchaser's use of the Products or Services. Purchaser agrees to indemnify, defend and hold harmless the Company, 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 Services, the Products and/or products or services derived there from, or (ii) any breach of purchaser's obligations.

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 and/or Services are the sole responsibility of, and shall be paid by purchaser. Purchaser shall satisfy all custom formalities.

I. ENTIRE AGREEMENT: These terms and conditions supersede any and all prior, contemporaneous or subsequent understandings, proposals, writings, oral representations, or other prior communications between the parties. 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 upon the date of delivery or two (2) business days after deposit in the mail, registered or certified, postage prepaid, and addressed to the Company or purchaser at the address provided by purchaser.

K. LICENSE; INTERNAL USE RESTRICTION: The software and hardware (collectively "Software") of the Products are provided pursuant to a non-exclusive, nontransferable and non-sublicense able 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 and conditions set forth herein. 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 the Company, 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 the Company in the Software or the Products. The Products and Software are the proprietary and the intellectual property rights of the Company and purchaser may be held legally responsible for any patent and copyright infringement or other violation of the Company's rights that is caused or encouraged by a failure to abide by the terms and conditions set forth herein. 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 the Company to enforce its rights hereunder.

M. OWNERSHIP. Any inventions and/or techniques for performing the Services which relate to the conduct of the Company's business are and shall remain the Company's exclusive property including, but not limited to, present and future documentation, scientific and technical data, test procedures and other information that is owned or licensed by the Company and that is not developed hereunder. The Company shall have the right to use concurrent control data as part of its general historical database.

N. GOVERNING LAW AND CONVENTION ON CONTRACTS FOR THE INTERNATIONAL SALE OF GOODS: This transaction 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 shall be heard in the courts of The Commonwealth of Massachusetts, USA.

NOTICE: If purchaser has agreed via a signed agreement with the Company to terms and conditions applicable to this sale of Product and/or Services, then those terms and conditions ("Specific Terms and Conditions") shall apply to this sale of Product and/or Services. In the event of a contradiction, the Specific Terms and Conditions shall prevail. If no Specific Terms and Conditions exist, then the terms and conditions contained herein and in the Company's sales catalog currently published on the Company website at www.criver.com (together "Terms and Conditions") shall apply to all sales of Products and Services by the Company and shall therefore constitute a sale agreement entered into between the Company and purchaser, irrespective of whether purchaser accepts these Terms and Conditions by a written acknowledgement, by implication, or by acceptance of Products and/or Services hereunder. The Terms and Conditions shall form part of any order placed by purchaser ("Order"). Any term or condition on any Order or other document submitted by purchaser shall be of no force or effect whatsoever. In particular, acceptance by the Company of an Order sent by purchaser shall not be deemed an acceptance of any conflicting or additional terms and conditions. The Company specifically rejects any different or additional terms and conditions proposed by purchaser, unless those terms and conditions are mutually agreed in writing.

General Terms and Conditions of Sale

Services: AccuGENX-ID®, AccuPRO-ID®, AccuBLAST®
Shipping to: Accugenix USA **or** the Charles River France facility

AccuGENX-ID® SAMPLE SUBMITTAL
A completed Identification Request Form (IRF) with authorized signature must accompany all samples shipped to either Accugenix location. The IRF may be accessed at http://www.accugenix.com/customer-support/sample-shipments/. Microbial identification can only be performed with pure colonies. Customers may ship plates with more than one colony type, provided that the colony (or colonies) to be identified is (are) well separated from other organisms. The organisms to be identified should be clearly marked and listed individually on the IRF to ensure testing will not be delayed. Sample submission options and sample preparation methods for each service can be accessed at http://www.accugenix.com/customer-support/preparing-bacterial-fungal-samples-testing-service/.

Additional fees may apply to:
- samples for which it is unknown whether the organism is a bacterium, mold or yeast
- samples that require isolation prior to testing
- customer samples retained beyond three (3) weeks
- samples that do not produce sequence data
- shipping of printed copies of reports.

Samples that are cancelled by a customer after testing has begun may incur full charge for identification.

AccuPRO-ID® SAMPLE SUBMITTAL
A completed IRF with authorized signature must accompany all samples shipped to either Accugenix location. The IRF may be accessed at http://www.accugenix.com/customer-support/sample-shipments/.

Microbial identification can only be performed with pure colonies. Customers may ship plates with more than one colony type, provided that the colony (or colonies) to be identified is (are) well separated from other organisms. The organisms to be identified should be clearly marked and listed individually on the IRF to ensure testing will not be delayed. Sample submission options and sample preparation methods for each service can be accessed at http://www.accugenix.com/customer-support/preparing-bacterial-fungal-samples-testing-service/.

Additional fees may apply to:
- samples for which it is unknown whether the organism is a bacterium, mold or yeast
- samples that require isolation prior to testing
- customer samples retained beyond three (3) weeks
- shipping of printed copies of reports

Samples that are cancelled by a customer after testing has begun may incur full charge for identification.

AccuGENX-ID® AND AccuPRO-ID® TAT REQUESTS AND RESULTS REPORTING

Accugenix USA
Turnaround time (TAT) is based on business days and begins on the day of receipt. If, upon arrival, the IRF is incorrect or incomplete, samples are mixed, contain no visible growth and/or require testing for clarification, the TAT will begin when isolated colonies, sufficient growth and/or additional information is received. Results are issued by 6:30 PM Eastern Time (ET) on the due date. If samples are received at Accugenix after 3:00 PM ET, TAT will begin the following business day. **Samples submitted for Same Day TAT require notification prior to their arrival.** Contact Technical Support at +1.302.292.8888 with the shipper and tracking number. Same Day TAT is available for samples received Monday through Friday. Same Day TAT samples must be shipped for arrival at Accugenix by 8:30 AM ET. Accugenix does not guarantee results by 5:00 PM ET for samples received later than 8:30 AM ET. Results for Same Day TAT samples received after 8:30 AM ET will be sent as soon as available; however, no later than 12:00 PM ET the next business day. Same Day TAT charge will apply. Should a Saturday Same Day TAT be required, contact Technical Support by 1:00 PM ET on the Friday before to schedule sample processing. Additional fees will apply.

Charles River France Facility
TAT is based on business days and begins on the day of receipt. If, upon arrival, the IRF is incorrect or incomplete, samples are mixed, contain no visible growth and/or require testing for clarification, the TAT will begin when isolated colonies, sufficient growth and/or additional information is received. Results are issued by 18:30 CET on the due date. If samples are received at the Charles River France facility after 13:00 CET, TAT will begin the following business day. **Samples submitted for Same Day TAT require notification prior to their arrival.** Contact Charles River France at +33 (0) 474 01 6932 with the shipper and tracking number. Same Day TAT is available for samples received Monday through Friday. Same Day TAT samples must be shipped for arrival at the Charles River France facility by 8:30 CET.* Accugenix does not guarantee results by 24:00 CET for samples received later than 8:30 CET. Results for Same Day TAT samples received after 8:30 CET will be sent as soon as available the next business day. Same Day TAT charge will apply.

**Earliest required delivery times are subject to change. Please check our web-site for details specific to your shipping location.*

AccuBLAST® SERVICE REQUEST FORM FILE SUBMITTAL
A completed AccuBLAST® Request Form (ARF) with authorized signature must accompany all sequence files sent to Accugenix. The ARF and data transfer information may be accessed at http://www.accugenix.com/customer-support/accublast-submission/. AccuBLAST® microbial identification can only be performed from files ending in .ab1 and must be obtained from a sequence-based ID system. The files should be the result of a sequence from pure colonies. If files are received at Accugenix after 12:00 PM ET, TAT will begin the following business day. Additional fees may apply to printed copies of reports. Submitted files that are cancelled by a customer after analysis work has begun will incur the full charge for identification.

AccuBLAST®TAT REQUESTS AND RESULTS REPORTING
TAT is based on business days and begins on the day and time that files are received at Accugenix. If, upon arrival, the ARF is incorrect or incomplete, the TAT will begin when the form is reconciled. Results are issued by 6:30 PM ET on the due date. **Sequence files submitted for Same Day TAT require notification prior to their arrival.** Same day TAT sequence files must be arrive at Accugenix by 12:00 PM ET. Accugenix does not guarantee results by 6:30 PM ET for samples received later than 12:00 PM ET. Same Day TAT is available for files received Monday through Friday. Should a Saturday Same Day TAT be required, contact Technical Support by 1:00 PM on the Friday before to schedule data analysis. Additional fees will apply.

MISCELLANEOUS
Resulting sample data processed by our Charles River, France facility will be securely transferred to Accugenix USA for analysis, review and reporting. Accugenix does not perform sterility testing. Failure to obtain a result does not indicate or imply sterility of sample. Once samples arrive, processing is initiated based on requested TAT. Special Project testing procedures developed between Accugenix and Customer may be outside of the scope of Accugenix-validated processes. Special Projects are performed with Customer's approval of the Special Project form, where the Special Project testing instructions and results are recorded. Accugenix does not perform any product release or compendial testing. Accugenix automatically emails 21 CFR Part 11 compliant reports on their due date. Printed reports are available upon request. Fees may apply. Accugenix USA recognizes most major United States holidays and will be closed. Contact Technical Support with questions regarding holiday observances and resulting effect on TAT. Charles River, France facility recognizes most major French holidays and will be closed. Contact Technical Support with questions regarding holiday observances and resulting effect on TAT. Accugenix sample retention policy is to hold customer samples for three (3) weeks post-result due date. Requests for longer retention should be made in writing to Technical Support at: accugenix-customersupport@crl.com. Pricing is subject to change without notice. Payment terms are net thirty (30) days.

Notes

Photo credit: page 27 © Dennis Kunkel Microscopy, Inc.

charles river | endotoxin and microbial detection

00.800.15.78.97.43 • eurendoexport@crl.com • www.criver.com