20 Microbial Solutions 16 Products & Services



Shafa Yekta Safe Co.Ltd. 09128305015-44426750-44443860 Web Site : www.EndosafeKit.Com

ENDOSAFE®

CELSIS®

JGENIX®





Charles River Microbial Solutions: Three powerful brands. One trusted partner.

Charles River Microbial Solutions

Honoring your responsibility to protect the integrity of your products requires a reliable partner at all critical junctures in the quality control process. We've purposely built our portfolio to bring you progressive products and services that deliver accurate, relevant and measurable data to fuel confident decisions on product quality for release.

As a proven innovator in the development of dependable, robust testing solutions, Charles River continues to set the standard for managing microbial quality control. In addition to the trusted Endosafe[®] and Accugenix[®] brands, the industry-leading Celsis® line of rapid microbial detection systems extends and unifies our core competencies, allowing us to provide the most comprehensive offering of microbial solutions from any single company.

Leading the market with products and services that meet the diverse needs of the pharmaceutical, home, beauty, dairy, beverage and food industries, Charles River Microbial Solutions is a partner you can count on to quickly and easily choose the right path at each and every crossroad to help ensure quality standards are met every time.



2016 Microbial Solutions Catalog Navigation

Click on the indicated icons throughout the catalog to view additional available resources.











Active links throughout the document will change the cursor icon from \diamondsuit to \circlearrowright .



Contents

02 Endotoxin Testing Systems

- 03 Endosafe[®] nexgen-PTS[™]
- 03 Endosafe®-PTS™
- 04 Endosafe®-MCS™
- 04 Endosafe® Nexus™
- **05** PTS[™]/MCS[™] LAL Cartridges
- 06 Endosafe[®] nexgen-PTS[™] Accessories
- 06 PTS[™]/MCS[™] Accessories
- 07 Endosafe[®]-PTS[™] Glucan Assay
- 07 Endosafe®-PTS™ Gram ID

14 LAL Reagents and Accessories

- 15 Kinetic Turbidimetric LAL
- 15 Kinetic Chromogenic LAL
- 16 Endosafe® Gel-Clot LAL
- 17 LAL Accessory Products
- 19 Proteus NoEndo™

08 Endotoxin Testing Instrumentation and Software

- 09 EndoScan-V[™] and Microtrend Software
- **09** Kinetic Plate Readers

10 Contract Endotoxin Testing Services

- 11 Method Development
- 11 Routine Endotoxin Determination
- 12 Product Validation
- 12 Product Release/Stability Testing
- 12 Oven Depyrogenation Validation
- **13** Endosafe[®] LAL Proficiency Test Program

20 Celsis[®] Microbial Detection

- 21 Celsis[®] Advance II[™] System
- 21 Celsis® Accel® System for Pharma
- 21 Celsis® Accel® System
- 21 Celsis® Innovate® System
- 21 PTS-Micro[™] Instrument
- 22 Celsis® Reagents
- 22 Celsis[®] Support Reagents and Consumables
- 23 Celsis® Accessories

24 Accugenix[®] Microbial Identification

- 25 AccuGENX-ID®
- 25 AccuBLAST®
- 26 AccuPRO-ID®
- 26 AccuGENX-ST®
- 26 Axcess™ System

28 Support Service Programs

- 29 Endosafe[®] nexgen-PTS[™]
- 29 Endosafe®-PTS™
- 29 Endosafe[®]-MCS[™]
- 30 Endosafe® Nexus™
- 30 Celsis® Accel®
- 30 Celsis® Advance™
- 30 Celsis® Advance II™
- 30 Celsis® Innovate®
- 30 Auto Sampler

31 Resources

31 Ordering Information32 Wako Reagents and Instrumentation



Endotoxin Testing Systems

Endotoxin testing is a critical checkpoint within many industries, in areas ranging from in-process 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.

Endosafe[®] nexgen-PTS[™]

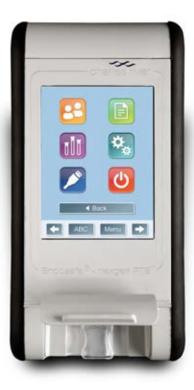
Our revolutionary Endosafe[®]-PTS[™] streamlined endotoxin testing by condensing all the necessary reagents into a single, disposable FDA-licensed cartridge and made portable, real-time endotoxin testing a reality. Our customer-focused approach and passion for innovation has driven our refinement of this highly flexible technology, resulting in the development of the Endosafe[®] nexgen-PTS[™]. Using the same USP/BET-compliant test as the first generation Endosafe[®]-PTS[™], we've implemented the advanced features of today's technology for the nexgen-PTS[™], including a user-friendly LCD color touchscreen, three levels for user profile management, increased internal reader storage capacity, wireless capabilities, and enhanced reporting features that address your needs for decreased sample preparation time, simplified data entry, reduced user variability and enhanced administration control.

ENDOSAFE® NEXGEN-PTS	CODE			
Endosafe® nexgen-PTS™ Ethernet cable One-year warranty Power supplies (US, EU & USB cable adaptor Mini-pipettor Operator manual				PTS150K
* Freight additional	001	Ţ.	Ĉ	

The Endosafe[®]-PTS[™]

The Endosafe®-PTS[™] produces quantitative endotoxin results in approximately 15 minutes. A 15-minute endotoxin assay means fewer bottlenecks, less downtime, improved sample management and faster production of product. Please see page 5 for information on how to order disposable cartridges for the PTS[™].





The Endosafe[®]-MCS[™]

The benchtop Endosafe[®]-MCS[™] enables you to test up to five samples simultaneously in 15 minutes. Greatly reducing downtime and improving overall efficiency, the MCS[™] also links to the EndoScan-V[™] and Microtrend software for sample tracking and trending.

ENDOSAFE

ENDOSAFE®-MCS™*	CODE
Power supply	MCS100K
Operator manual	
Endosafe®-MCS™ package	
MCS™ reader	
EndoScan-V™ software	MCS550K
Power supply	
Operator manual	
IQ/OQ/PQ	
EndoScan-V™ software	M1250
Microtrend database-trending software	M804
* Freight additional	

The Endosafe[®] Nexus[™]

Recognizing high-throughput challenges in central QC labs, our R&D team developed the first endotoxin testing system capable of testing 48 to 60 samples with minimal preparation and supervision. Ideal for high-volume testing of samples that require dilutions, the Nexus[™] utilizes LAL cartridge technology, a state-of-the-art liquid handling system and simple data management to reduce variability and the need for subsequent investigations.

ENDOSAFE® NEXUS™*				CODE
Nexus™ robotic system				
MCS [™] reader				MR650
EndoScan-V™ software				MINUJU
Computer				
Nexus™ robotic system				
EndoScan-V [™] software				MR550
Computer				
Sterilized conductive 300 μ L tips case				MD200
(480 per pack) (5,760 per case)				MR300
Sterilized conductive 1 mL tips case (480 per pack) (3,840 per case)				MR1000
* Freight additional				
		ŕ		
, U	ليت			
.7016				

PTS[™]/MCS[™] LAL Cartridges

All of our rapid endotoxin testing instruments utilize our FDA-licensed cartridges for batch release testing, 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
	0.1	PTS201F
10 single peaks of contridence (FDA licenced)	0.05	PTS2005F
10 single packs of cartridges (FDA-licensed)	0.01	PTS2001F
	0.005	PTS20005F
	0.1	PTS201
10 single packs of cartridges (unlicensed)	0.05	PTS2005
	0.01	PTS2001

* Freight additional

ENDOSAFE®-PTS™ CARTRIDGES*	SENSITIVITY EU/ML	CODE
	0.05	PTS5505F
Multi-packs of 25 cartridges (5/pouch) (FDA-licensed)	0.01	PTS5501F
	0.005	PTS55005F

* Freight additional

Note: The cartridges must be used within two hours of breaking the pouch's seal.

ENDOSAFE®-PTS™ CARTRIDGES'	CODE
10 single packs of inhibition/enhancement screening cartridges ⁺	PTS220

* Freight additional

† Inhibition/enhancement screening cartridges are not licensed by the FDA.





$\textbf{Endosafe}^{\text{\tiny $^{\circ}$}} \textbf{ nexgen-PTS}^{\text{\tiny $^{\circ}$}} \textbf{ Accessories}$

ENDOSAFE® NEXGEN-PTS™ ACCESSORIES	CODE
Endosafe® nexgen-PTS™ power cable UK	PTS112
Endosafe® nexgen-PTS ™ power cable EU	PTS113
Ethernet cable	PTS114
USB micro cable adaptor	PTS115
Zebra Technologies QLn™ 320 printer kit	
Zebra printer Power supply (US, EU, UK)	PTS320K
USB cable	1100201
1 roll printer paper	
Zebra printer USB cable	PTS321
Zebra printer AC power adaptor	PTS322
Zebra printer paper	PTS325
Flexpoint™ HS-1M Series 9/Series N barcode scanner	PTS375

PTS[™]/MCS[™] Accessory Products

PTS™/MCS™ ACCESSORIES	CODE
PC to PTS™ cable	PTS108
PTS™ AC adaptor	PTS109
PTS™ power supply cable	PTS110
PTS™ USB to serial converter	PTS111
Seiko® thermal printer	PTS300
Thermal paper for Seiko® printer	PTS301
Seiko® printer cable	PTS302
Epson® dot matrix printer	PTS310
PTS™ 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 μ L, disposable)	PTS400
Protective reader case	PTS600
Eppendorf [®] 25 μ L pipettor	PTS700
PTS™ blank cartridges	PTS200
* Freight additional	

* Freight additional

$\textbf{Endosafe}^{*}\textbf{-}\textbf{PTS}^{\texttt{m}}\textbf{ Glucan Assay and Gram ID}$

Additional rapid testing products that utilize the PTS[™] for microbiological testing are available for glucan contamination and Gram determination. The PTS^m Glucan Assay quantifies β -glucans, leading to better process monitoring and faster out-of-specification resolutions in less than 30 minutes. The PTS[™] Gram ID informs the user whether an isolate is a Gram-negative or -positive bacteria, or confirms yeast or mold, in about 3 minutes.

ENDOSAFE [®] -PTS™*					CODE
Endosafe®-PTS™ instrument					
Integrated software					
Power supply					PTS100K
Adaptor cord Mini-pipettor					
Operator manual					
Epson® dot matrix printer					PTS310
EndoScan-V™ software					M1250
* Freight additional					
ENDOSAFE®-PTS™ CARTRIDGES					CODE
Glucan cartridges					RMMGS1000
Gram ID cartridges					LRMMGI100
		ŕ	<u> </u>	ŕ	
	-	_	<u> </u>		
				1	
				()	
				Aller	
				2	
					1
				())	12.00
				2	
					-
					1º
					criver.com/microbialsolut

Endotoxin Testing Instrumentation and Software

It takes innovation to offer kinetic endotoxin systems that are not only accurate but intuitive, incorporating robust data management with reliable hardware and expert technical support.

> Our kinetic LAL instrumentation and software is designed specifically to help reduce variability and increase operational efficiencies by achieving quantitative results and incorporating flexible configuration capabilities.





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.

ENDOSCAN-V™ AND MICROTREND SOFTWARE	CODE	
Endosafe [®] EndoScan-V [™] software (compatible with BioTek [®] plate readers, PTS [™] , MCS [™] and Nexus [™])	M1250	
EndoScan-V [™] software validation package	TS600	
Electronic signature	M1300	
Microtrend database-trending software (compatible with BioTek [®] plate readers, PTS™ and MCS™)	M804	
Microtrend software validation package	TS11000	

Kinetic Plate 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.

BIOTEK® KINETIC PLATE READERS AND ACCESSORIES	CODE
BioTek® incuba <mark>t</mark> ing microplate reader (with 340, 405, 450, 490, 630 nm filters)	M200
Calibration plate for BioTek [®] reader	M400
Calibration plate recertification (valid for one year) – BioTek®	TS950
BioTek® bulb	M700

PLATE READER OPTIONS	CODE
On-site training on reader/software*	TS400
Microplate stand	M1000
Marking template for 96-well plate	M1100
Computer Package – Laptop	MCP100
Computer Package – Desktop	MCP200
* Travel expenses applicable	

criver.com/microbialsolutions 9



Contract Endotoxin Testing Services

Our technical services laboratory can support you in performing your critical tests to help streamline the process to final product release.

By partnering with Charles River, you can be confident that our experienced specialists can help improve the compliance and efficiency of your endotoxin testing program and help you to achieve control, consistency and precision in your laboratory. Our laboratories offer a variety of cGMP testing and support services and are FDA registered as of December 2009.

METHOD DEVELOPMENT	CODE
Method development	TS100
ROUTINE ENDOTOXIN DETERMINATION	CODE
Routine endotoxin determination, non-regulated, any method	
PTS™	
Gel-clot	TS700
Kinetic chromogenic	
Kinetic turbidimetric	

GEL-CLOT TECHNIQUE'	CODE
Product validation – 3 lots	TS203
Product validation – 1 lot	TS201
Product release or stability test*	TBET1

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

KINETIC CHROMOGENIC TECHNIQUE	CODE
Product validation – 3 lots	TS203
Product validation – 1 lot	TS201
Product release or stability test*	TBET1

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

KINETIC TURBIDIMETRIC TECHNIQUE	CODE
Product validation – 3 lots	TS203
Product validation – 1 lot	TS201
Product release or stability test*	TBET1

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

PTS™ TECHNIQUE	CODE
Product validation – 3 lots	TS203
Product validation – 1 lot	TS201
Product release or stability test*	TBET1

* 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.	- / //
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	TS2013X
ADDITIONAL SERVICES	CODE
Special COA testing	TCOA1
On-site training*	TS400
SOP and protocol writing	TS800

* Travel expenses applicable

Purpose. Process. Participation.

The Charles River Proficiency Test Program (PTP) is a quality assurance tool for limulus amebocyte lysate (LAL) users that provides confidential quarterly audits of LAL test proficiency. For almost 20 years, laboratories looking to verify working procedures through an external source have been using the Charles River PTP to ensure internal quality assurance, verify methods, report validations and identify trends and possible training needs.

The program, which is available at the start of every quarter, is open to any LAL user looking to verify working procedures through an external source with no restrictions on methodology, reagents or instrumentation. Charles River has worked with almost 400 participating laboratories across 24 countries to improve LAL testing measures. Start dates for the Proficiency Test Program include: week 6 (February 2016), week 16 (April 2016), week 30 (July 2016) and week 41 (October 2016).

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

Endosafe[®] LAL Proficiency Test Program

PROFICIENCY TESTING PROGRAM	CODE
1 study	TPTP-1
2 studies	TPTP-2
3 studies	TPTP-3
4 studies	TPTP-4
Each additional sample	ТРТРХ







LAL Reagents and Accessories

Our team has developed and optimized a range of quantitative and qualitative LAL formulations that provide increased sensitivity, greater linearity and superior interference resistance.

Our innovative Endosafe[®] LAL reagents are licensed by the FDA for product release, and our accessory products are all certified for the appropriate LAL testing requirements. These highquality accessories impart control, consistency and precision to the LAL laboratory, thereby minimizing invalid results and repeat testing.

Kinetic Turbidimetric LAL

Our FDA-licensed kinetic turbidimetric reagents yield quantitative endotoxin values when used with an incubating reader equipped with endotoxin-measuring software. KTA is licensed for both kinetic and gel-clot analyses and permits a direct correlation between methods. KTA² is a second-generation kinetic turbidimetric reagent that offers faster reaction times and routinely tests to sensitivities of 0.005 EU/mL.

KINETIC TURBIDIMETRIC LAL[†] 50-TEST VIAL (5.2 ML)

50-TEST VIAL (5.2 ML)	CODE
KTA ²	R19000
	R15015
КТА	R15003
	R15006

* Maximum sensitivity can be achieved under specific test conditions and with specific accessories only. † Reserves of LAL reagents and matching CSE are offered for a period of one year.

Kinetic 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 [†]	CODE
Endochrome-K™ 256-test kit	
8 × 3.2 mL vials 2 × 10 ng control standard endotoxin 3 × 30 mL LAL reagent water	R1708K
Endochrome-K [™] 320 tests 10 x 3.2 mL vials	R1710
* Maximum sensitivity can be achieved under specific test conditions and with specific accessories only.	R17100
Endochrome-K [™] 3200 tests 100 x 3.2 mL vials * Maximum sensitivity can be achieved under specific test conditions and with specific accessories only. † Reserves of LAL reagents and matching CSE are offered for a period of one year. ENDPOINT CHROMOGENIC REAGENTS Endpoint chromogenic kit (140 tests)	R17100 CODE

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	SENSITIVITY EU/ML	CODE
	0.015	R15015
	0.03	R15003
50-test vial (5.2 mL)	0.06	R15006
	0.125	R11012
	0.25	R11025
10 single-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
	0.03	R13003
Cincile test vial (0.0 ml.)	0.06	R13006
Single-test vial (0.2 mL)	0.125	R13012
	0.25	R13025

RAPID SINGLE-TEST LAL VIALS (0.2 ML)*	SENSITIVITY EU/ML	CODE
Rapid single-test vial (50-test)†	0.06 or 0.25	R13500
Rapid single-test vial (50-test) [†]	0.25 or 1	R13600
Rapid positive product control (50-test)		PC200

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

† Dual sensitivity based on assay run time.

LAL Accessory Products

We provide all the necessary accessory products required to run an LAL test.

CONTROL STANDARD ENDOTOXIN (CSE) E. coli AND REFERENCE STANDARD		
ENDOTOXIN (RSE)	CODE	PACKAGING
CSE – 500 ng per vial*	E110	6/pack
CSE – 10 ng per vial*	E120	6/pack
Positive control (for single test)	PC100	25/pack
Reference standard endotoxin	E150	—
* Lot-specific Certificate of Analysis included		
CXE KIT'		CODE
CXE Extended CSE dilution kit		
1 × 10 ng CSE 1 × 60 mL stabilizing solution 1 pack of 11 of 16 × 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 MgSO4, 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

REACTION TUBES	CODE	PACKAGE
10×75 mm capped flint glass tubes in a box	T100	50/pack
10×75 mm flint glass tubes wrapped in aluminum foil	T200	50/pack
10×75 mm borosilicate glass tubes wrapped in aluminum foil (appropriate for use with tube readers)	T400	50/pack
8 × 75 mm borosilicate glass tubes wrapped in aluminum foil (only for use with tube readers)	T500	50/pack
10×75 mm screw-cap borosilicate glass tubes in a box	TL1200	50/pack

DILUTION TUBES	CODE	PACKAGE
12×75 mm borosilicate glass tubes wrapped in aluminum foil	TL1000	50/pack
13×100 mm borosilicate glass tubes wrapped in aluminum foil	Т300	50/pack
16×90 mm screw-cap borosilicate glass tubes in a box	TL700	70/pack

SAMPLING TUBES	CODE	PACKAGE
18×150 mm borosilicate glass tubes wrapped in aluminum foil	T600	14/pack
16×160 mm screw-cap borosilicate glass tubes in a box	TL800	100/pack



DEPYROGENATED GLASS PIPETTES	CODE	PACKAGE OF 10
1 mL wrapped in aluminum foil	P100	5 packs
2 mL wrapped in aluminum foil	P200	5 packs
5 mL wrapped in aluminum foil	P500	5 packs
10 mL wrapped in aluminum foil	P1000	5 packs

D100	50/pack
D200	100/pack
	D200

96-WELL ENDOSAFE® PLATES (INDIVIDUALLY WRAPPED)*	CODE
96-well polystyrene plate (certified to 0.005 EU/mL)	M9005

* Tissue culture treated

Proteus NoEndo[™] Spin Column Kits^{*}

Designed for simple, rapid removal of endotoxin from a wide range of protein solutions.

RAPID SINGLE-TEST LAL VIALS (0.2 ML)	CODE	KIT QUANTITY
Proteus NoEndoµ (Micro) 2-column kit (includes 0.2 mL NoEndo™ resin vial)	ERE2Micro	2
Proteus NoEndoM (Mini) 2-column kit (includes 2 × 0.25 mL NoEndo™ resin vials)	ERE2M	2
Proteus NoEndoS (Standard) 2-column kit	ERE2S	2
Proteus NoEndoHC (High Capacity) 2-column kit	ERE2HC	2
Proteus NoEndoµ (Micro) 24-column kit (includes 2.4 mL NoEndo™ resin vial)	ERE24Micro	24
Proteus NoEndoM (Mini) 12-column kit (includes 12 × 0.25 mL NoEndo™ resin vials)	ERE12M	12
Proteus NoEndoS (Standard) 12-column kit	ERE12S	12
Proteus NoEndoHC (High Capacity) 12-column kit	ERE12HC	12

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









Celsis[®] Microbial Detection Systems

Speed products to market while ensuring product quality and meeting safety standards with Celsis[®] rapid microbial detection systems.

Celsis[®] rapid methods are a proven alternative to the slow, expensive and subjective traditional testing that often adds days, or weeks to your production cycle. Robust, easy-to-use Celsis[®] systems reduce time to result for quarantined product, achieving shorter production cycles and improved market responsiveness. You'll appreciate earlier notice of contamination and faster recovery time, and reduce your lab waste, water usage and energy consumption – all equaling substantial savings in working capital and inventory expenses.

For pricing on all Celsis[®] systems, reagents and accessories, please contact us at: celsis.support@crl.com.

Celsis[®] Advance II[™] System

Rugged and robust, the Celsis[®] Advance II[™] System is designed to meet the needs of busy microbiology labs. Testing up to 120 assays per hour, the luminometer has the high throughput needed for medium- to large-scale manufacturing facilities, and the intuitive Advance II.im software is easy to learn and easy to use.



Celsis® Accel® System for Pharma

Testing 30 assays per hour, the Accel[®] for Pharma is well suited for laboratories with small to medium assay volume requirements. A compact version of our reliable Advance II[™] instrument, the Accel[®] for Pharma fits into any microbiology laboratory and the included AccelPharma.im software offers a suite of powerful data management tools for easy tracking and trending.

CELSIS® ACCEL® SYSTEM FOR PHARMA

UODE
 7460288

Celsis® Accel® System

Testing 30 assays per hour, the Accel[®] is well suited for laboratories with small to medium assay volume requirements. A compact version of our reliable Advance II[™] instrument, the Accel[®] fits into any microbiology laboratory. Included with the system, Accel.im software offers a simple, intuitive interface with the luminometer for precise injection of reagent and easy system management.

CELSIS® ACCEL® SYSTEM	CODE
	7460287

Celsis® Innovate® System

Designed specifically for dairy, beverage and food companies, the Innovate[®] provides high throughput with the reliability companies need for maximum uptime. Innovate im software features a user-friendly interface and data management.

CELSIS® IN	NOVATE™ SYSTEM	CODE
<u>_</u> .		220050

Please contact us for more information on our available consumables and pricing.

CUDE

PTS-Micro™ Instrument

The PTS-Micro[™] is a revolutionary technology platform to streamline your bioburden testing and reduce your laboratory footprint by efficiently and rapidly detecting for bioburden in multiple samples simultaneously in an intuitive, self-contained system.

PTS-MICRO™ INSTRUMENT	CODE
PTS-Micro™ scanner	
Power supply NUC computer Accessory cables Capillary holder Operator manual	RMM100

Please contact us for more information on our available consumables and pricing.



Celsis® Microbial Detection Reagents

Our advanced reagent technology is second to none, offering the fastest time to result on the market. Produced in an ISO 9001-certified facility, you can expect the sensitivity and reliability you need to ensure product quality.

AS1320
AS4220
AS1310
AS4210
82010
82050



Support Reagents and Consumables

Additional reagent kits required for maintenance and support are produced in the same ISO-certified facility to the same standards as our primary reagent kits.

SUPPORT REAGENTS AND CONSUMABLES	CODE
ATP positive control kit	1291483
Daily wash & rinse kit	1290142N
Monthly maintenance kit for Innovate®	1290500
Monthly maintenance and cleaning kit for Accel $^{\ensuremath{\circledast}}$ and Advance II $^{\mbox{\tiny M}}$	92828

Celsis® Accessories

We've partnered with reliable suppliers that offer high quality at an affordable price to provide you with the convenience of ordering numerous accessories from the name you know and trust: Charles River.

ACCESSORIES	CODE
Pipette 20-200 μL	91184
Pipette 100-1,000 μL	91192
Pipette 5-50 μ L	91200
Rack 80 cuvettes	92080
Priming cuvettes, 75 mm (1,000)	1280052
Advance cuvettes (1,000)	1280139
150 mL containers (120 ct)	1280200
250 mL containers (48 ct)	1280250
ATP-free pipette tips, 200 μ L (10 x 96 pcs)	93678
ATP-free pipette tips, 1,000 μ L (10 x 100 pcs)	93686
Non-sterile pipette tips, 200 μ L (10 x 96 pcs)	93679
Non-sterile pipette tips, 1,000 μ L (10 x 100 pcs)	93687
Wide-bore pipette tips, 200 μ L (10 x 96 pcs)	93676
Glass beads 0.5 mm	AS9001
Antifoam B emulsion	AS9003
Linear shaker 115V	AS128001
Linear shaker 220V	AS128002
Microtiter plates	620140000



Accugenix® Microbial Identification

Our microbial identification services are defined by our industry-leading proprietary libraries.

Coupled with scientific expertise and data analysis, the Charles River Accugenix[®] line of microbial identification and strain typing products and services provides accurate, rapid and cost-effective solutions in line with global regulatory standards.



AccuGENX-ID[®]

Genotypic Identification of Bacteria and Fungi (rDNA Sequencing)

The most accurate and reproducible method for identifying unknown microorganisms.

AccuGENX-ID[®] genotypic identification utilizes the industry's leading proprietary libraries and methods to identify microorganisms. The sequence-based identification techniques for bacteria (16S 500 bp) 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 500 BP)	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
Ę		

AccuBLAST[®]

Analysis & Interpretation of 16S Raw Data Sequence Files (*.ab1)

The AccuBLAST[®] service is ideal for laboratories that process and sequence their own bacterial isolates, but prefer to have their MicroSeq[®] data assembled, analyzed and compared against our industry-leading 16S library for bacteria. We leverage sophisticated problem-solving methods to help customers reconcile otherwise inaccurate or inconsistent data.

TURNAROUND TIME (TAT)	TEST CODE (16S)
Same day	AccuBLAST-0
1 day	AccuBLAST-1
2 days	AccuBLAST-2

AccuPRO-ID[®]

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

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 in accuracy of 30-40% over existing phenotypic methods. AccuPRO-ID[®] offers a first-in-industry polyphasic approach to microbial identification utilizing proteotypic MALDI-TOF mass spectrometry technology supported by our AccuGENX-ID[®] 16S rDNA sequencing method at no additional cost.

TURNAROUND TIME (TA	Т)	1	TEST CODE BACTERIA	
Same day			AccuPRO-ID-0	
1 day			AccuPRO-ID-1	
2 days			AccuPRO-ID-2	
5 days			AccuPRO-ID-5	
Ţ	Ĉ	▶		

AccuGENX-ST[®]

Sequence-based Strain Typing

As a complement to our sequence-based microbial identification services, we offer our AccuGENX-ST[®] multi- and single-locus sequence typing (MLST, SLST) service for strain-level characterization and tracking of bacterial and fungal isolates.

TURNAROU	JND TIME (TAT)	TEST CODE
	1 day	AccuGENX-ST-1
2	2 days	AccuGENX-ST-2
5	days	AccuGENX-ST-5
	ļ. Ĉ	
.762.7016		

Axcess[™] System for Microbial Identification

The Axcess[™] System pairs the precision of the MALDI Biotyper instrument with the industry-leading Accugenix[®] proprietary microbial libraries through a secure online network. Based on MALDI-TOF mass spectrometry, the MALDI Biotyper is a paradigm shift which has become widely accepted across industry segments as the next generation of microbial identification. While conventional identification methods are time-consuming and often require ancillary tests, the Axcess[™] System allows for instantaneous identification of isolated colonies from a plate.

AXCESS™ MALDI BIOTYPER-CM PACKAGE	CODE
Axcess™ MALDI Biotyper-CM package	
Microflex LT/SH benchtop MALDI-TOF mass spectrometer	
Starter kit for MALDI-TOF MS	
Barcode scanner for MALDI Biotyper	AXC550
Reference PhysioCare pack software package	100000
Bruker MALDI Biotyper	
Database-CD reference library for MALDI Biotyper	
Software with the Bruker MBT-WEB solution	
MBT compliance assistant module	AXC1500
Axcess™ authorization	AXC-SL1000
Axcess™ classification	AXCESS-0

AXCESS™ MALDI BIOTYPER-CM REAGENTS	CODE
Bacterial test standard (BTS)	AXC110
Matrix HCCA	AXC150
MSP 96 steel target plate	AXC9600
MSP adapter for MALDI Biotarget 48	AXC4800AD
MALDI Biotarget 48 disposable target plate	AXC4800

AXCESS™ MALDI BIOTYPER-CM SERVICES	CODE
Complete CARE Priority	AXC1000
Complete CARE	AXC900
Axcess™ qualification panel	AXC 509
Initial qualification MBT	AXC403B
Software qualification/Methods validation	AXC502
Annual OQ/PV	AXC400B

Support Service Programs

Every purchase of our Endosafe[®], Accugenix[®] and Celsis[®] products is backed by the experts within our Service Contract and Support team.

From regular maintenance and annual calibration to on-demand service contracts, our dedicated professionals are a single point of contact for all of your service requirements, providing superior, timely service delivery and a simple, streamlined process for obtaining support. Choose from the plans below, or contact our team for a program tailored to suit your needs.





Support Service Programs

Code	Product Name	Contract Type
ENDOSAFE®-P1	ſS™	
PTS500	Endosafe [®] -PTS™	Annual calibration certification
PTS500FS	Endosafe [®] -PTS™	Annual calibration certification: Full service
PTS502	Endosafe [®] -PTS™	IQ/OQ/PQ kit
PTS502S	Endosafe [®] -PTS™	IQ/OQ/PQ on-site
PTS503	Endosafe [®] -PTS™	On-demand repair services: Labor only
PTS505	Endosafe [®] -PTS™	Annual calibration certification: On-site service
PTS505FS	Endosafe [®] -PTS™	Annual calibration certification: On-site full service
PTS506	Endosafe [®] -PTS™	Each additional unit for annual calibration certification
ENDOSAFE® NE	EXGEN-PTS™	
PTS900	Endosafe [®] nexgen-PTS™	Annual calibration certification
PTS900FS	Endosafe [®] nexgen-PTS™	Annual calibration certification: Full service
PTS902	Endosafe [®] nexgen-PTS™	IQ/OQ/PQ kit
PTS902S	Endosafe [®] nexgen-PTS™	IQ/OQ/PQ on-site
PTS 903	Endosafe [®] nexgen-PTS™	On-demand repair services: Labor only
PTS905	Endosafe [®] nexgen-PTS™	Annual calibration certification: On-site service
PTS905FS	Endosafe [®] nexgen-PTS™	Annual calibration certification: On-site full service
ENDOSAFE®-M	CS™	
MCS575	Endosafe [®] -MCS™	IQ/OQ/PQ document
MCS502	Endosafe [®] -MCS™	IQ/OQ/PQ service and kit
MCS503	Endosafe [®] -MCS™	On-demand repair services: Labor only
MCS504	Endosafe [®] -MCS™	One-year warranty
MCS500	Endosafe [®] -MCS™	Annual qualification service
MCS505	Endosafe [®] -MCS™	Annual on-site qualification service plus one-year warranty
MCS500FS	Endosafe [®] -MCS™	Annual qualification: Full service
MCS506	Endosafe [®] -MCS™	On-site basic service

Support Service Programs (continued)

Code	Product Name	Contract Type
ENDOSAFE® NEXU	S™	
MR502	Endosafe [®] Nexus™	IQ/OQ/PQ service
MR502K	Endosafe [®] Nexus™	IQ/OQ/PQ kit
MR503	Endosafe [®] Nexus™	On-demand repair services: Labor only
MR504	Endosafe [®] Nexus™	On-site basic service
MR500	Endosafe® Nexus™	Annual service
MR500FS	Endosafe® Nexus™	Annual service: Full service
KINETIC PLATE RE	ADERS	
TS500	EndoScan-V™	Qualification of reader/software
TS550	EndoScan-V™	Microplate reader IQ/OQ/PQ (document only)
TS502	EndoScan-V™	Microplate reader IQ/OQ/PQ on-site
CELSIS® ACCEL®		
RD500B	Celsis [®] Accel [®]	On-site basic preventive maintenance only
RD500S	Celsis [®] Accel [®]	On-site standard
RD500P	Celsis [®] Accel [®]	On-site premier
CELSIS® ADVANCE	тм	
RD600B	Celsis [®] Advance™	On-site preventive maintenance only
RD600S	Celsis [®] Advance [™]	On-site standard
RD600P	Celsis [®] Advance™	On-site premier
CELSIS® ADVANCE	Штм	
RD700B	Celsis [®] Advance II™	On-site preventive maintenance only
RD700S	Celsis [®] Advance II™	On-site standard
RD700P	Celsis [®] Advance II™	On-site premier
CELSIS® INNOVAT	E®	
RD800B	Celsis [®] Innovate [®]	On-site preventive maintenance only
RD800S	Celsis [®] Innovate [®]	On-site standard
RD800P	Celsis [®] Innovate [®]	On-site premier
AUTO SAMPLER		
RD900B	Auto Sampler	On-site basic
RD900S	Auto Sampler	On-site standard
RD900P	Auto Sampler	On-site pro

Resources

With a growing list of laboratory and agent locations in North America, Europe, South Korea, Australia, India and Singapore, the Charles River Microbial Solutions team serves customers in over 400 countries, providing customer support in 46 languages across 24 time zones.



Charles River Endotoxin Detection Products and Services 1023 Wappoo Road, Suite 43-B Charleston, SC 29407

Charles River Microbial Identification Products and Services 223 Lake Drive Newark, DE 19702

Celsis® Microbial Detection Products and Services 1023 Wappoo Road, Suite 43-B Charleston, SC 29407

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

Click to request a quote.

Click to request a demo.

Phone: 1.843.402.4900 Toll Free: 1.800.762.7016 Fax: 1.843.766.7576

Phone: 1.302.292.8888 Toll Free: 1.800.886.9654 Fax: 1.302.292.8468

Phone: 1.843.402.4900 Toll Free: 1.800.762.7016 Fax: 1.843.766.7576 Endosafe[®] customer sales department: endosafecustomerservice@crl.com

Endosafe[®] technical support: endo-comments@crl.com

PTS-Micro™ support: pts-microcomments@crl.com

Sales and literature requests: askcharlesriver@crl.com

Accugenix[®] services technical support: accugenix-customersupport@crl.com

Celsis® products and services: celsis.support@crl.com



Wako Reagents and Instrumentation

For almost 20 years, Charles River has offered Wako's world-renowned product line. With a reputation for highquality products and services, the Wako reagents and instrumentation are offered below.

Wako Toxinometer®

The Wako Toxinometer[®] is a versatile tube reader that performs kinetic turbidimetric, gel-clot and kinetic chromogenic assays within one instrument using LAL and SLP reagents. The test is performed in reaction tubes that are exclusive to Wako.

TUBE READER STERILIZED CONSUMABLES	CODE	PACKAGING
Toxinometer® ET-6000 expansion module U	297-33529	16 wells
Toxinometer® ET-6000 expansion module E	294-33539	16 wells
Toxinometer® ET 6000/U	293-33509	1 unit
Toxinometer® ET 6000/E	293-33519	1 unit
Toxinometer® ET 6000/U nonpart 11	293-33989	1 unit
Toxinometer® ET 6000/E nonpart 11	293-33969	1 unit

The PYROSTAR[™] ES-F Series

The PYROSTAR™ ES-F series of reagents is an endotoxin-specific line of limulus amebocyte lysate products that are formulated to be used either qualitatively as a gel-clot reagent or quantitatively as a kinetic-turbidimetric reagent.

PYROSTAR™ ES-F MULTI KIT (2 ML)	SENSITIVITY EU/ML	CODE	PACKAGING
	0.015	WPEK4-20015	1 kit
	0.03	WPEK4-20003	1 kit
80-test PYROSTAR™ kit (4 vials x 20 tests)	0.06	WPEK4-20006	1 kit
	0.125	WPEK4-20125	1 kit
	0.25	WPEK4-20025	1 kit

PYROSTAR™ ES-F MULTI KIT (5.2 ML)	SENSITIVITY EU/ML	CODE	PACKAGING
	0.015	WPEK4-50015	1 kit
	0.03	WPEK4-50003	1 kit
200-test PYROSTAR™ kit (4 vials x 50 tests)	0.06	WPEK4-50006	1 kit
	0.125	WPEK4-50125	1 kit
	0.25	WPEK4-50025	1 kit
PYROSTAR™ ES-F MULTI (2 ML)	SENSITIVITY EU/ML	CODE	PACKAGING
	0.015	WPEM-20015	1 box
	0.03	WPEM-20003	1 box
20-test PYROSTAR™ vial x 100	0.06	WPEM-20006	1 box
	0.125	WPEM-20125	1 box
	0.25	WPEM-20025	1 box
PYROSTAR™ ES-F MULTI (5.2 ML)	SENSITIVITY EU/ML	CODE	PACKAGING
	0.015	WPEM-50015	1 box
	0.03	WPEM-50003	1 box
50-test PYROSTAR™ vial x 100	0.06	WPEM-50006	1 box
	0.125	WPEM-50125	1 box
	0.25	WPEM-50025	1 box
PYROSTAR™ ES-F SINGLE TEST	SENSITIVITY EU/ML	CODE	PACKAGING
Single-test PYROSTAR ™ kit (25 tests) (KTA quantitative range [EU/mL] 0.001 to 10)	0.015	WPESK-0015	25-test kit
PYROSTAR™ ES-F/PLATE (2 ML)	SENSITIVITY EU/ML	CODE	PACKAGING
PYROSTAR™ ES kit 0.01-10 (160 tests) (KTA quantitative range [EU/mL] 0.01 to 10)	0.015	WPEPK4-20015	1 kit

Accessories

LIMULUS PS TEST	CODE	PACKAGING
Limulus PS single test	299-54501-HS	20-test kit
PS accessory kit	294-33311-HS	1 kit
ENDOTOXIN EXTRACTING	CODE	PACKAGING
Endotoxin extracting solution	293-51601-HS	4 x 10 mL
TUBE READER STERILIZED CONSUMABLES	CODE	PACKAGING
BioClean tip Wako 200 II	291-35021	200 µL x 100 pcs
BioClean tip Wako 1000 II	298-35031	1,000 μ L x 100 pcs
BioClean tip Wako extend S II	294-35011	200 µL x 100 pcs
Limulus test tube S w/aluminum cap	292-32751 (12 x 75 mm)	80 pcs
Limulus test tube S	293-26551 (12 x 75 mm)	100 pcs
Aluminum cap S	293-28251 (14.7 x 18 mm)	100 pcs
LIMULUS COLOR KY TEST	CODE	PACKAGING
Color KY single-test kit – 25 tests	291-53601-HS	1 kit
Color KY kinetic kit – 60 tests	291-53101-HS	1 kit
CONTROL STANDARD ENDOTOXIN	CODE	PACKAGING
Control standard endotoxin 500 ng	CSE4037-5006	1 pack/6 vials
LYSATE REAGENT WATER	CODE	PACKAGING
Lysate reagent water 100 mL	LRW-12100	12 x 100 mL
LYSATE REAGENT WATER	CODE	PACKAGING
Lysate reagent water 30 mL	LRW-2030	20 x 30 mL

For our General Terms and Conditions of Sale, please reference our dedicated web page here: **www.criver.com/microbialgroupterms**

Notes

Notes

We've changed our name, **not our passion.**

Existing customers and contracts for our Endosafe[®], Accugenix[®] and Celsis[®] products and services will continue to receive the same dedicated service and support from our newlynamed Microbial Solutions team.

With a global footprint, decades of experience and a commitment to partnership, Charles River Microbial Solutions delivers state-of-the-art technologies with unmatched service and expertise.



Shafa Yekta Safe Co.Ltd. 09128305015-44426750-44443860 Web Site : www.EndosafeKit.Com

