Certificate of Registration
of Quality Management System to I.S. EN ISO 9001:2015

Charles River Microbial Solutions

Unit 649 Greenogue Business Park
Rathcoole
Co. Dublin
Ireland

NSAI certifies that the aforementioned company has been assessed and deemed to comply with the provisions of the standard referred to above in respect of:-

The distribution of equipment, reagents for bacterial endotoxin (Endosafe®) and microbial detection (Celsis®) assays through activities performed within Logistics, Technical Services and Instrument services. The execution of Accugenix microbial identification services by DNA sequencing and MALDI-TOF MS and technical services

Approved by:
Stewart Hickey
Head - Business Excellence, NSAI

Registration Number: **19.7193**
Original Registration: **3 October 2018**
Last amended on: **7 September 2021**
Valid from: **2 October 2021**
Remains valid to: **2 October 2024**

This certificate remains valid on condition that the Approved Quality Management System is maintained in an adequate and efficacious manner. NSAI is a partner of IQNet – the international certification network (www.iqnet-certification.com)

Partner of:

All valid certifications are listed on NSAI's website – www.nsai.ie. The continued validity of this certificate may be verified under "Certified Company Search"

NSAI (National Standards Authority of Ireland), 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T: +353 1 807 3800 E: info@nsai.ie www.nsai.ie

Digitally signed by Dorgopol Iulian
Date: 2024.03.26 11:31:46 EET
Reason: MoldSign Signature
Location: Moldova

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

NSAI has issued an IQNet recognised certificate that the organisation:

Charles River Microbial Solutions
Unit 649 Greenogue Business Park
Rathcoole
Co. Dublin
Ireland

has implemented and maintains a

Quality Management System

for the following scope:

The distribution of equipment, reagents for bacterial endotoxin (Endosafe®) and microbial detection (Celsis®) assays through activities performed within Logistics, Technical Services and Instrument services. The execution of Accugenix microbial identification services by DNA sequencing and MALDI-TOF MS and technical services

which fulfils the requirements of the following standard:

I.S. EN ISO 9001:2015

Issued on: 2 October 2021
First issued on: 3 October 2018
Expires on: 2 October 2024

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IE-19.7193

Alex Stoichitoiu
President of IQNet

Stewart Hickey
Head – Business Excellence, NSAI

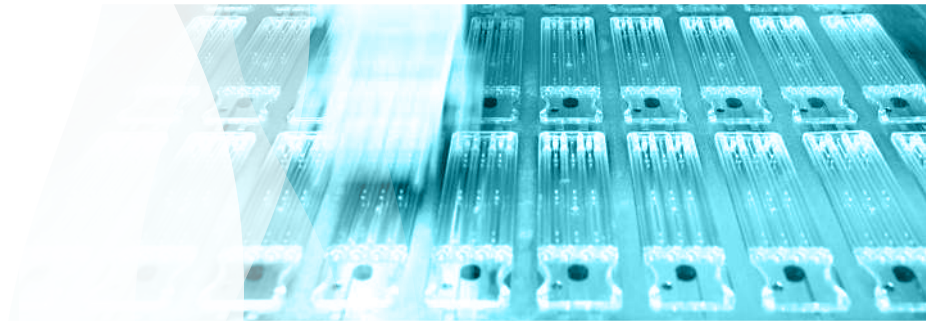
IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy* CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica* IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* *NYCE*-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

charles river

Microbial Solutions

Products & Services | 2018



Charles River

Microbial Solutions

Protecting the integrity of your products demands rigorous quality control, a critical task made easier with the help of a reliable partner. Charles River is that partner, offering innovative, flexible solutions and technical expertise to support you every step of the way. We've purposely built our portfolio to bring you progressive products and services that deliver accurate, relevant, and reliable data to fuel confident decisions on product quality and contamination control.

We lead the market with products and services that meet the diverse needs of the pharmaceutical, home, beauty, dairy, beverage, and food industries. Our unique combination of Endosafe® endotoxin testing, Celsis® rapid microbial detection, and Accugenix® microbial identification and strain typing keeps your manufacturing operations running efficiently and smoothly, lowers your cost to manufacture, and protects your reputation.

2018 Microbial Solutions Catalog Navigation

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

video **webpage** **webinar** **poster** **tech sheet** **white paper**

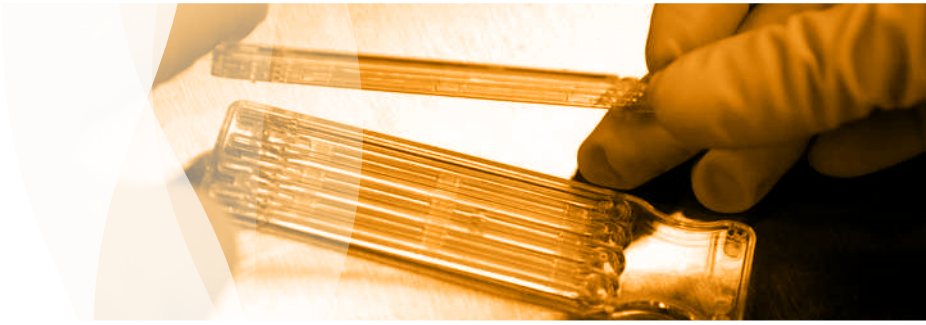
Active links throughout the document will change the cursor icon from ⇧ to ☝.

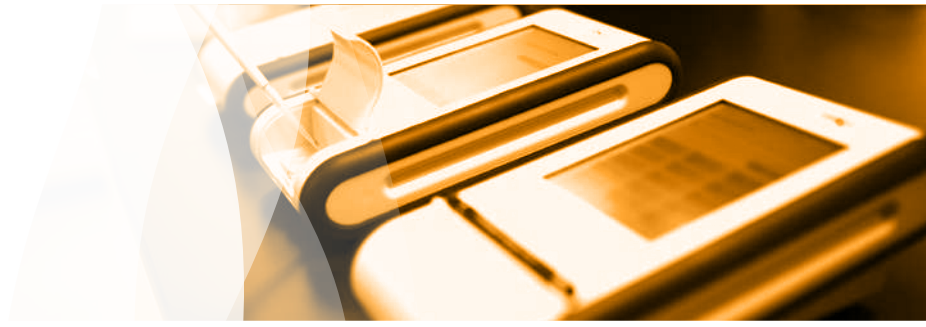
Contents

Endotoxin Testing Systems

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

Our Endosafe® systems simplify endotoxin testing. Flexible solutions meet the needs of every customer regardless of sample volume or industry. From in-process testing to final lot release, our easy-to-use Endosafe® cartridge technology products increase efficiency in the LAL laboratory by delivering rapid, accurate results. Every system we sell is backed by our skilled technical team who can provide training, maintenance, and support.





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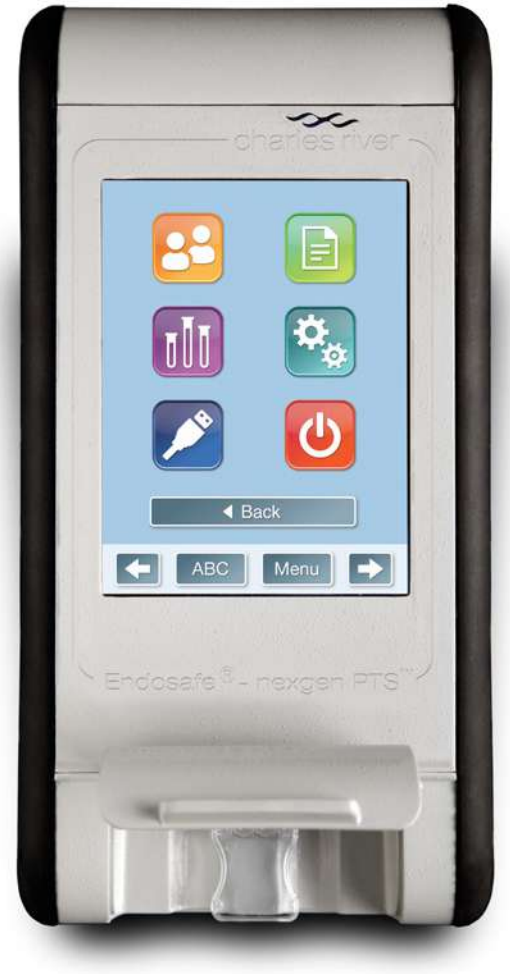
Endosafe® nexgen-PTS™

The Endosafe® nexgen-PTS™ is a rapid, point-of-use handheld spectrophotometer that uses USP-BET-compliant disposable cartridges for accurate, convenient, and real-time endotoxin testing, glucan concentration determination, and Gram identification. The enhanced features address your needs for decreased assay run time, simplified data entry, reduced user variability, and heightened administration control. The addition of a User Management function allows the system to be 21 CFR Part 11 compliant-ready. The nexgen-PTS™ is the system of choice for small volume, point-of-sample testing on the manufacturing floor.

Endosafe® nexgen-PTS™	Code
Endosafe® nexgen-PTS™ instrument Ethernet cable One-year warranty Power supply USB cable adapter Mini-pipettor Stylus	PTS150K



Endosafe® nexgen-MCS™

Clients with higher volume testing needs can choose the Endosafe® nexgen-MCS™. Using the same FDA-licensed cartridges as the nexgen-PTS™, the nexgen-MCS™ features five individual spectrophotometers to test up to five samples at once, with results in just 15 minutes. Readings are sent via Ethernet to a connected desktop computer, where our 21 CFR Part 11 compliant ready EndoScan-V™ software (Version 5.5.5 SP1 and higher) measures and reports endotoxin results.

Endosafe® nexgen-MCS™	Code
Endosafe® nexgen-MCS™ instrument Power supply Ethernet cable One-year warranty	MCS150K
Endosafe® nexgen-MCS™ package nexgen-MCS™ instrument EndoScan-V™ software Power supply One-year warranty IQ/OQ/PQ	MCS650K
EndoScan-V™ software	M1250

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 per automation session with minimal preparation and supervision. Ideal for high volume undiluted testing as well as labor-intensive 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 nexgen-MCS™ instrument Nexus™ integrated software Computer Anti-static mat	MR650
Nexus™ robotic system Nexus™ integrated software Computer Anti-static mat	MR550
Sterilized conductive 300 µL tips case (5,760 per case)	MR300
Sterilized conductive 1 mL tips case (3,840 per case)	MR1000

Endosafe® LAL Cartridges

The Endosafe® cartridge technology is our innovative response to our customers' need for higher sensitivity and faster quantitative results. Designed to optimize and refine our use of LAL, the cartridge technology uses only 1/20th of the raw material required for a traditional test. The cartridge technology eliminates a significant amount of the accessories required for traditional LAL methods while reducing time-consuming preparation and technician variability. For nexgen-MCS™ users, we offer convenient, economical cartridge multi-packs. For planning purposes, please note that cartridges must be used within 2 hours of breaking the pouch seal.

Endosafe® LAL Cartridges	Sensitivity EU/mL	Code
10 single packs of cartridges (FDA-licensed)	0.1	PTS201F
	0.05	PTS2005F
	0.01	PTS2001F
	0.005	PTS20005F
10 single packs of cartridges (unlicensed: for R&D use only)	0.1	PTS201
	0.05	PTS2005
	0.01	PTS2001
Multi-packs of 25 cartridges (5/pouch) (FDA-licensed)	0.05	PTS5505F
	0.01	PTS5501F
	0.005	PTS55005F
10 single packs of inhibition/enhancement screening cartridges*		PTS220

*Inhibition/enhancement screening cartridges are not licensed by the FDA

Endosafe® Glucan Assay and Gram ID Cartridges

Additional rapid testing products that utilize both the original (PTS100/MCS100) and the nexgen (PTS150/MCS150) systems for microbiological testing are available for glucan contamination and Gram determination. With results in less than 30 minutes, the Glucan Assay quantifies β-glucans, leading to better process monitoring and faster out-of-specification resolutions. The Gram ID indicates whether an isolate is a Gram-negative or Gram-positive bacteria, or confirms yeast or mold, in about 3-7 minutes.

Endosafe® Cartridges	Code
Beta-Glucan cartridges (10/pack)	RMMGS1000
Gram ID cartridges (10/pack)	LRMMGI100

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

Accessory Products

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 adapter	PTS115
Zebra Technologies QLn™ 320 printer kit Zebra printer Power supply and cable USB cable 1 roll printer paper	PTS320K
Zebra printer USB cable	PTS321
Zebra printer AC power adapter	PTS322
Zebra printer paper	PTS325
Zebra Symbol barcode scanner	FGD-000012
Stylus	PTS117
nexgen-PTS™ protective reader case	PTS609

PTS™/MCS™ Accessories	Code
Epson® printer cable	PTS311
Ribbon for Epson® printer	PTS312
Paper roll for Epson® printer	PTS313
Continuous roll label for Epson® printer	PTS314
Eppendorf® 25 µL pipettor	PTS700
PTS™ blank cartridges (quantity 2)	PTS200

Endotoxin Testing Instrumentation and Software

Charles River offers kinetic microplate readers that incorporate robust data management with reliable hardware and expert technical support to provide accurate and intuitive data analysis.

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.

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Charles River Cortex™ Data Management & Analysis Software

Creating Centralized Control for a Decentralized Approach

Maintaining the long-term safety of a manufacturing environment while meeting the demands of compliance is a microbial quality control manager's top priority. The need to investigate out-of-specification (OOS) results continues to be one of the most commonly observed cGMP issues during quality control laboratory inspections. Having access to accurate, relevant, and reliable data is essential to support confident decisions on product quality. Recent FDA warning letters and new global guidance documents communicate the increasing requirements on data integrity, making many organizations aware of existing gaps and deficiencies in their data and reporting.

Charles River Cortex™ provides an integrated solution to securely consolidate, query, and analyze all real-time endotoxin data for necessary internal QA and FDA trending reports. The decentralized, multi-client solution provides complete QA/QC instrument oversight. This allows remote PC access (with Cortex client software installed) to the same results database and server. Customers can compile and manage data from any of the Endosafe® rapid testing platforms, microplate readers, and tube readers into a unified data infrastructure to gain complete insight on their manufacturing operation and process in order to make informed, confident decisions. Cortex allows users to proactively manage and monitor the operational integrity of the entire facility's endotoxin instrument equipment fleet including component effectiveness, calibration schedules, and system readiness within a single, end-to-end risk management environment.

Charles River Cortex™	Code
Charles River Cortex™ Software	M1600
Annual Maintenance Contract	AMC1600
Charles River Cortex™ License/Device Authorization per Endosafe®-PTS™ (PTS100K) device	M1601
Charles River Cortex™ License/Device Authorization per Endosafe® nexgen-PTS™ (PTS150K) device	M1602
Charles River Cortex™ License/Device Authorization per Endosafe® MCS™ (MCS100K)	M1603
Charles River Cortex™ License/Device Authorization per Endosafe® nexgen-MCS™ (MCS150K)	M1604
Charles River Cortex™ License/Device Authorization for Plate Reader/Tube Reader	M1605
Charles River Cortex™ IQ/OQ Service	AMC502S

EndoScan-V™ Endotoxin-Measuring Software

Enabling accurate, intuitive data analysis, EndoScan-V™ performs endotoxin calculations and generates secure data files and batch reports for product release as required by the FDA. The software's flexible networking configuration works with Microsoft Excel™, your LIMS, or with centralized databases. EndoScan-V™ is also fully compatible with our Cortex™ software, allowing generated data to automatically transfer. The EndoScan-V™ user interface is available in English, French, and German, and includes comprehensive online documentation and IQ/OQ/PQ guidelines.

EndoScan-V™ Software	Code
Endosafe® EndoScan-V™ software (compatible with BioTek® and Tecan® plate readers, original and nexgen test systems)	M1250
EndoScan-V™ software validation package	TS600
Electronic signature	M1300

Kinetic Plate Readers

We provide compact, multi-use spectrophotometers that 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® incubating 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
Power supply	M800
Power cable	M801

Plate Reader Options	Code
On-site training on reader/software*	TS400
Computer package – laptop	MCP100
Computer package – desktop	MCP200

* Travel expenses additional

Contract Endotoxin Testing Services

Our technical services laboratory can help streamline your testing operations for a smooth process to final product release.

Charles River's experienced specialists can help you improve the compliance and efficiency of your endotoxin testing program. Our FDA-registered laboratories offer a variety of cGMP testing and support services to help you achieve control, consistency, and precision in your testing environment.

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Contract Endotoxin Testing Services

Method Development	Code
Method development	TS100

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

Gel-Clot, Kinetic Chromogenic, and Kinetic Turbidimetric Techniques	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.

Contract Endotoxin Testing Services (continued)

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 (≤ 10 vials)	TS203
Oven validation/testing of challenge vials (> 10 vials)	TS203

Additional Services	Code
Special Certificate of Analysis (COA) testing	TCOA1
On-site training*	TS400
SOP and protocol writing	TS800

* Travel expenses additional

Endosafe® LAL Proficiency Test Program

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

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.

Charles River's Endosafe® LAL reagents are licensed by the FDA for product release, and all of our accessory products are certified for the appropriate LAL testing requirements. These deliver extreme precision and reliability, minimizing invalid results and the need to retest.

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Kinetic Turbidimetric LAL (KTA)

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. KTA^2 is a second-generation kinetic turbidimetric reagent that offers faster reaction times and routinely tests to sensitivities of 0.005 EU/mL. Specified accessories and test conditions are required to achieve maximum sensitivity.

Kinetic Turbidimetric LAL† 50-Test Vial (5.2 mL)	Sensitivity EU/mL	Code
KTA^2 (used for kinetic testing only)		R19000
KTA	0.015	R15015
	0.03	R15003
	0.06	R15006

† Reserves of LAL reagents and matching Control Standard Endotoxin (CSE) are offered for a period of one year.

Kinetic Chromogenic LAL (KCA)

Endochrome-K™ LAL facilitates your endotoxin screening with its ease of use and unique reagent stability. Our optimized KCA LAL offers a 0.001 EU/mL limit of detection and provides greater linearity and superior interference resistance for quantitative endotoxin values. Specified accessories and test conditions are required to achieve maximum sensitivity.

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
Endochrome-K™ 3200 tests 100 x 3.2 mL vials	R17100

† Reserves of LAL reagents and matching Control Standard Endotoxin (CSE) are offered for a period of one year.

Endpoint Chromogenic Reagents	Code
Endpoint chromogenic kit (140 tests) 5 × 1.4 mL vials of chromogenic LAL 1 × 10 mg vial of chromogenic substrate S-2423 2 × 2 ng vials of endotoxin 2 × 30 mL vials of LAL reagent water 1 × 15 mL 0.05 M vial of Tris buffer	R160K

Endosafe® Gel-Clot LAL

The gel-clot assay is a simple, qualitative method of endotoxin detection, best suited for low-volume laboratories. Endosafe® lysate features a firm gel over a wide range of sensitivities. The reagent is buffered for enhanced interference resistance.

Gel-Clot LAL	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
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 (0.2 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 line 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)	Packaging	Code
CSE – 500 ng per vial*	6/pack	E110
CSE – 10 ng per vial*	6/pack	E120
Positive control (for single test)	25/pack	PC100
RSE	—	E150

* Lot-specific Certificate of Analysis included when reagents are purchased together.

Extended CSE (CXE) Dilution Kit*	Code
CXE 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 when reagents are purchased together.

LAL Reagent Water (in plastic bottle)*	Package	Code
30 mL bottle (< 0.001 EU/mL)	12/case	W130
50 mL bottle (< 0.001 EU/mL)	12/case	W120
100 mL bottle (< 0.001 EU/mL)	12/case	W110
500 mL bottle (< 0.001 EU/mL)	6/pack	W150

* Certificate of Quality included.

LAL Accessory Products (continued)

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

* Please contact Technical Support before using buffers. Additional buffers are available for specific testing needs.

Endotoxin Indicators*	Code
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	Package	Code
10 × 75 mm capped flint glass tubes, boxed	50/pack	T100
10 × 75 mm flint glass tubes, in foil	50/pack	T200
10 × 75 mm borosilicate glass tubes, in foil (appropriate for use with tube readers)	50/pack	T400
8 × 75 mm borosilicate glass tubes, in foil (only for use with tube readers)	50/pack	T500
10 × 75 mm screw-cap borosilicate glass tubes, boxed	50/pack	TL1200

LAL Accessory Products (continued)

Tubes	Package	Code
12 × 75 mm borosilicate glass tubes, in foil	50/pack	TL1000
13 × 100 mm borosilicate glass tubes, in foil	50/pack	T300
16 × 90 mm screw-cap borosilicate glass tubes, boxed	70/pack	TL700
18 × 150 mm borosilicate glass tubes, in foil	14/pack	T600
16 × 160 mm screw-cap borosilicate glass tubes, boxed	100/pack	TL800

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

Eppendorf® Pipette Tips	Package	Code
Eppendorf® tips (20-200 µL,* individually wrapped)	50/pack	D100EA
Eppendorf® tips (20-200 µL, individually wrapped)	100/pack	D200

* Certificate of Analysis not included.

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

* Tissue culture treated.

Rapid Microbial Detection

Speed products to market while ensuring that they meet quality and safety standards with Celsis® rapid microbial detection.

The proprietary adenosine triphosphate (ATP) bioluminescence technology employed by Celsis® rapid detection systems offers speed and reliability that traditional methods just can't match. Robust, easy-to-use Celsis® systems reduce time to result for quarantined product, achieving shorter production cycles and improved market responsiveness. Early notice of contamination allows for a faster response and recovery time and can reduce inventory hold times resulting in a substantial working capital savings. Furthermore, Celsis® can streamline lab processes, improve data integrity, and minimize lab waste, water usage, and energy consumption.

Celsis Advance II™

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.im™ software offers a suite of powerful data management tools for tracking and trending results.

	Code
Celsis Advance II™ System	7456004

Celsis Accel® System

With a throughput of 30 assays per hour, the Celsis Accel® is well suited for laboratories with small to medium assay volume requirements. A compact version of our reliable Celsis Advance II™ instrument, the Celsis Accel® fits into any microbiology laboratory and includes the intuitive and easy to use Accel.im™ software.

	Code
Celsis Accel® System	7460288

Celsis® Microbial Detection Reagents

Our advanced AMPiScreen® reagent technology offers the fastest time to result on the market by using a series of enzyme-based reactions to amplify even the lowest concentrations of microbial ATP.

Primary Reagents	Code
AMPiScreen® 800 assay kit	AS1310
AMPiScreen® 400 assay kit	AS4210

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 and Cleaning kit	92828

Celsis® Accessories

Accessories	Code
Pipette, 20-200 µL	91184
Pipette, 100-1,000 µL	91192
Pipette, 5-50 µL	91200
Rack, 80 cuvettes	92080
Priming cuvettes, 75 mm (1,000)	1280052
Advance cuvettes (1,000)	1280139
150 mL containers (120 ct)	1280200
ATP-free pipette tips, 200 µL (10 x 96 pcs)	93678
ATP-free pipette tips, 1,000 µL (10 x 100 pcs)	93686
Glass beads, 0.5 mm	AS9001
Antifoam B emulsion	AS9003
Linear shaker, 115V	AS128001
Linear shaker, 220V	AS128002

Laboratory Services

Charles River offers a variety of laboratory services to support your product evaluation needs, including product suitability and methods development. Please contact your sales representative for additional information.

Microbial Identification Services

Our Accugenix® microbial identification services are powered by our industry-leading proprietary libraries.

Superior data lead to superior control. Accugenix® microbial identification and strain typing products and services optimize your environmental monitoring program by providing accurate, rapid, and cost-effective solutions in line with global regulatory standards. Sample identification data is stored on the regulatory-compliant and secure customer web portal that includes complementary tracking and trending features. The Accugenix® customer web portal meets the requirements of 21 CFR Part 11 and complies with GAMP5 standards for validation of automated systems. Our growing list of service laboratories includes locations in the United States, France, Ireland, India, South Korea, and Singapore.

AccuGENX-ID®

Genotypic Identification of Bacteria and Fungi (rDNA Sequencing)

The most accurate and reproducible method for identifying unknown microorganisms, AccuGENX-ID® utilizes comparative DNA sequencing of the 16S rRNA gene in bacteria and the ITS2 rRNA region in fungi through our BacSeq and FunITS identifications. This sequencing method is independent of the health or growth conditions of the isolate; samples can be viable or nonviable cultures, or simply genomic DNA from your microbe. For each sample submitted for identification, the resulting DNA sequence is compared against our validated, highly relevant libraries for bacteria and fungi. Our sequencing services are the most accurate method for identification of unknown microorganisms, which is critical for contamination investigations.

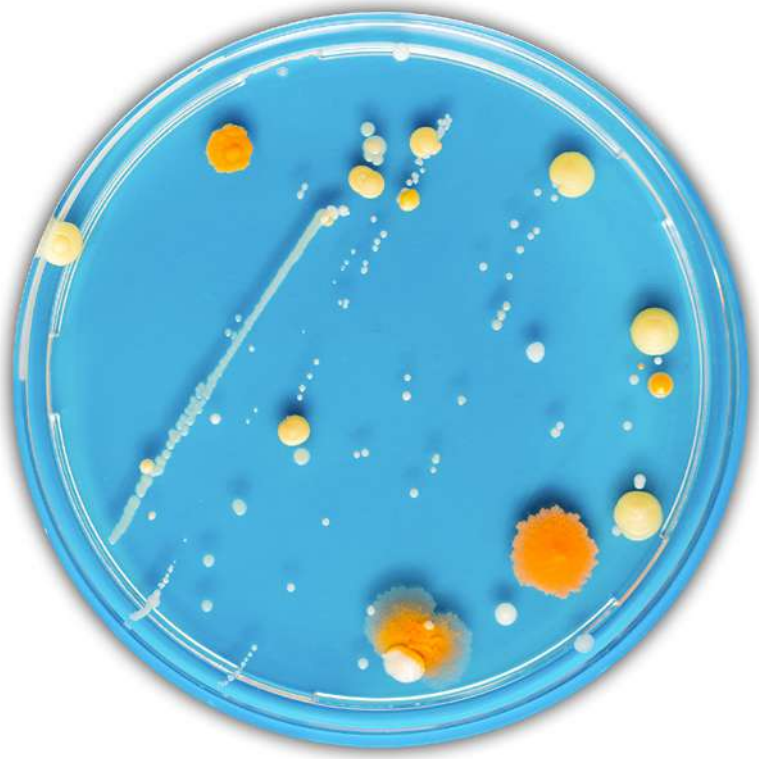
Turnaround Time (TAT)	Test Code Bacteria (16S 500 bp)	Test Code Fungi (ITS2)
Same day	BacSeq-0	FunITS-0
1 day	BacSeq-1	FunITS-1
2 days	BacSeq-2	FunITS-2
5 days	BacSeq-5	FunITS-5

AccuPRO-ID®

Proteotypic Identification of Bacteria and Yeast (MALDI-TOF Backed by AccuGENX-ID®)

AccuPRO-ID® offers a first-in-industry polyphasic approach to microbial identification utilizing proteotypic MALDI-TOF mass spectrometry technology supported by our AccuGENX-ID® sequencing method at no additional cost. We have been offering this technology for industrial applications since 2010 under our cGMP quality system, longer than any other contract laboratory in the industry, and are also accredited for ISO 17025. We are experts in the identification of isolates from industrial manufacturing environments and provide accurate species-level identifications that can give you a high level of confidence in your ability to effectively track and trend data that are pertinent to your environmental monitoring program.

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



AccuBLAST®

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

Exclusively designed for customers who have invested in the MicroSEQ® identification system, this service is provided for users who recognize the value of the more extensive, validated Accugenix® library. The AccuBLAST® service employs our own unrivaled sequence library and expert data analysis to generate meaningful reports, allowing us to deliver accurate reports with very short turnaround times.

Turnaround Time (TAT)	Test Code (16S)
Same day	AccuBLAST-0
1 day	AccuBLAST-1
2 days	AccuBLAST-2

AccuGENX-ST®

Sequence-Based Strain Typing

Root cause analysis in production facilities often requires differentiating microorganisms at the strain level. Strain typing allows you to ascertain how closely related an organism is to other isolates from the same species observed in past events. Strain typing can also be used for production strain verification, especially for verification of master cell bank (MCB) and working cell bank (WCB) strains.

Turnaround Time (TAT)	Test Code
5 days	AccuGENX-ST-5

Axcess® System for Microbial Identification

The Axcess® system pairs the precision of the MALDI Biotyper instrument with the industry-leading Accugenix® proprietary microbial library through a secure online network. While conventional identification methods are time-consuming and often require ancillary tests, the Axcess® system allows for nearly instantaneous identification of isolated colonies from a plate. Subscription fees for the Accugenix® MALDI-TOF Reference Library are determined based on expected annual usage. The Axcess® Premium Plan offers a worry free solution that includes AccuGENX-ID® backup service while the Axcess® Basic Plan allows flexibility to choose when additional sequencing identification is needed.

Axcess® MALDI Biotyper-CM System	Code
Axcess® MALDI Biotyper-CM package Starter Kit for MALDI-TOF MS Barcode scanner for MALDI Biotyper Reference Physiocare Pack (tips and pipettes) Software Package MALDI Biotyper 4.0 SR1 MALDI SW Security Pack for SW 4.0	AXC550

Axcess® MALDI Biotyper Smart CM System	Code
Axcess® MALDI Biotyper Smart CM package Starter Kit for MALDI-TOF Smart MS Barcode scanner for MALDI Biotyper Reference Physiocare Pack (tips and pipettes) Software Package MALDI Biotyper 4.0 SR1 MALDI SW Security Pack for SW 4.0	AXC650

Axcess® Plans	Code
Axcess® Basic plan	AXCB01
Axcess® Premium plan Includes a No Match Sample Guarantee for samples with no ID	AXCP01

High Volume Accessories	Code
MBT Galaxy System (GP)	AXC81655
MBT Pilot System (GP)	AXC81880

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	AXC4800AD
MALDI Biotarget 96 disposable target plate (20/pack)	AXC9600D

Required with Purchase	Code
Initial qualification MBT (IQ/OQ-PV) (Bruker performs)	AXC403B
Software qualification/Methods validation	AXC502
Axcess® authorization	AXC-SL1000

Annual Instrument Service Agreement Options	Code
Complete CARE	AXC900
Complete CARE Priority	AXC1000
Warranty Plus CARE (available first year only)	AXC700
Annual OQ/PV with service agreement	AXC400B
Annual OQ/PV without service agreement	AXC404B

QC Custom Solutions

Our partnership with Microbiologics, an industry leader in the production of QC microorganisms, offers characterization, preservation, and manufacturing solutions for your USP testing. Isolates are supplied in a convenient, ready-to-use format for QC testing. Please contact your sales representative for additional information.

Instrument Service and Support

Every purchase of our Endosafe® 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 your needs.

To request information on our discounted annual payment plans or extended 3-year and 5-year service agreement options (availabe for most products), please email us at: **MicroinstruRFQ@crl.com**

charles river | Microbial Solutions

Instrument Service and Support

Endosafe®-PTS™	Code
Annual calibration certification	PTS500
Annual calibration certification: Full service	PTS500FS
IQ/OQ/PQ kit	PTS502
IQ/OQ/PQ on-site	PTS502S
On-demand repair services: Labor only	PTS503
Annual calibration certification: On-site service	PTS505
Annual calibration certification: On-site full service	PTS505FS
Each additional unit for annual calibration certification	PTS506
Each additional unit for annual calibration certification: Full service	PTS506FS

Endosafe® nexgen-PTS™	Code
Annual calibration certification	PTS900
Annual calibration certification: Full service	PTS900FS
IQ/OQ/PQ kit	PTS902
IQ/OQ/PQ on-site	PTS902S
On-demand repair services: Labor only	PTS903
Annual calibration certification: On-site service	PTS905
Annual calibration certification: On-site full service	PTS905FS
Each additional unit for annual calibration certification	PTS906
Each additional unit for annual calibration certification: Full service	PTS906FS

Instrument Service and Support (continued)

Endosafe®-MCS™	Code
IQ/OQ/PQ document	MCS575
IQ/OQ/PQ service and kit	MCS502
On-demand repair services: Labor only	MCS503
Annual qualification service	MCS500
Annual on-site qualification service plus on-site basic service	MCS505
Annual qualification: Full service	MCS505FS
Each additional unit for annual qualification service	MCS506
On-site full service	MCS506FS

Endosafe® nexgen-MCS™	Code
IQ/OQ/PQ document	MCS975
IQ/OQ/PQ service	MCS902
IQ/OQ/PQ kit	MCS902K
On-demand labor	MCS903
Annual qualification service	MCS900
Annual on-site qualification service plus on-site basic service	MCS905
Annual qualification: Full service	MCS905FS
Additional units for annual calibration certification	MCS906
Additional units for annual qualification plus on-site basic service	MCS906A
Additional units for annual calibration certification: Full service	MCS906FS

Instrument Service and Support (continued)

Endosafe® Nexus™	Code
IQ/OQ/PQ service	MR502
IQ/OQ/PQ kit	MR502K
On-demand repair services: Labor only	MR503
On-site basic service	MR505
Annual service	MR500
Annual service: Full service	MR500FS

Charles River Cortex™	Code
IQ/OQ service	AMC502S
Annual maintenance	AMC1600

Kinetic Plate Readers	Code
On-site training for readers/software: Half day	SVSTRNG-H
On-site training for readers/software: Full day	SVSTRNG-F
Qualification of reader/software	TS500
Each additional qualification of reader/software	TS506
BioTek® reader/software annual qualification with bulb	TS500BF
BioTek® reader/software additional qualification	TS506BF
Microplate reader IQ/OQ/PQ (document only)	TS550
Microplate reader IQ/OQ/PQ on-site	TS502
EndoScan-V™ software validation package	TS600
Calibration plate recertification Biotek® (valid for one year)	TS950
Additional calibration plate recertification Biotek® (valid for one year)	TS956
Kinetic reader service contract	TS2700

Instrument Service and Support (continued)

Celsis Accel®	Code
On-site basic preventive maintenance only	RD500B
On-site standard	RD500S
On-site premier	RD500P

Celsis Advance™	Code
On-site preventive maintenance only	RD600B
On-site standard	RD600S
On-site premier	RD600P

Celsis Advance II™	Code
On-site preventive maintenance only	RD700B
On-site standard	RD700S
On-site premier	RD700P

Celsis Innovate®	Code
On-site preventive maintenance only	RD800B
On-site standard	RD800S
On-site premier	RD800P

Celsis® Mini	Code
In-house preventive maintenance only	RD200MINI

Celsis® Cellscan	Code
In-house preventive maintenance only	RD200CSCAN

Instrument Service and Support (continued)

Auto Sampler	Code
On-site basic	RD900B
On-site standard	RD900S
On-site pro	RD900P

Miscellaneous	Code
Billable service loaner rate	RDLOAN
Standard hourly labor rate	LABOR
Standard hourly travel rate (50% of standard labor rate)	TSTRAVEL
On-site training: Half day	CSVSTRNG-H
On-site training: Full day	CSVSTRNG-F

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.

Ordering Information

Charles River Endotoxin and Microbial Detection Products and Services

1023 Wappoo Road, Suite 43-B
Charleston, SC 29407

Phone: 1.843.402.4900
Toll Free: 1.800.762.7016
Fax: 1.843.766.7576

Charles River Microbial Identification Products and Services

614 Interchange Boulevard
Newark, DE 19711

Phone: 1.302.292.8888
Toll Free: 1.800.886.9654
Fax: 1.302.292.8468

To obtain product literature or technical documentation, please visit our website:
www.criver.com/microbialsolutions

Endosafe® customer service & sales:
microbialsolutionsCSDUS@crl.com

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

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

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

For all general inquiries: **askcharlesriver@crl.com**

Wako Reagents and Instrumentation

Charles River is proud to offer trusted technologies from Wako Chemicals USA, Inc.

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 reagents. The test is performed in reaction tubes that are exclusive to Wako.

Tube Reader Sterilized Consumables	Packaging	Code
Toxinometer® ET-6000/U, Part 11 set	1 unit	293-33509
Toxinometer® ET-6000/U, Expansion Module	16 wells	297-33529
Toxinometer® ET-6000/U, Non-Part 11 set	1 unit	293-33989

The PYROSTAR™ ES-F Series

The PYROSTAR™ ES-F series of reagents is an endotoxin-specific line of LAL products that are formulated to be used either qualitatively as a gel-clot reagent or quantitatively as a kinetic-turbidimetric reagent. Quantitative sensitivities range from 0.01-10 EU/mL for 0.03-0.25 gel clot and 0.001-10 EU/mL for 0.015 gel clot.

PYROSTAR™ ES-F Multi Kit (2 mL)	Sensitivity EU/mL	Code
80-test PYROSTAR™ kit 4 vials x 20 tests and (1) 500 ng CSE vial	0.015	WPEK4-20015
	0.03	WPEK4-20003
	0.06	WPEK4-20006
	0.125	WPEK4-20125
	0.25	WPEK4-20025

PYROSTAR™ ES-F Multi Kit (5.2 mL)	Sensitivity EU/mL	Code
200-test PYROSTAR™ kit 4 vials x 50 tests and (1) 500 ng CSE vial	0.015	WPEK4-50015
	0.03	WPEK4-50003
	0.06	WPEK4-50006
	0.125	WPEK4-50125
	0.25	WPEK4-50025

PYROSTAR™ ES-F Multi (2 mL)	Sensitivity EU/mL	Code
20-test PYROSTAR™ vial x 100	0.015	WPEM-20015
	0.03	WPEM-20003
	0.06	WPEM-20006
	0.125	WPEM-20125
	0.25	WPEM-20025

PYROSTAR™ ES-F Multi (5.2 mL)	Sensitivity EU/mL	Code
50-test PYROSTAR™ vial x 100	0.015	WPEM-50015
	0.03	WPEM-50003
	0.06	WPEM-50006
	0.125	WPEM-50125
	0.25	WPEM-50025

PYROSTAR™ ES-F Single Test	Sensitivity EU/mL	Code
Single-test PYROSTAR™ kit (25 tests) KTA quantitative range [EU/mL] 0.001 to 10, and (1) 500 ng CSE vial	0.015	WPESK-0015

PYROSTAR™ ES-F/Plate (2 mL)	Sensitivity EU/mL	Code
PYROSTAR™ ES KTA quantitative range [EU/mL] 0.001 to 10, and (1) 500 ng CSE vial	0.015	WPEPK4-20015

Limulus Color KY Test (colorimetric/chromogenic assay)	Code
Color KY single-test kit 25 tests and (1) 500 ng CSE vial	291-53601-HS
Color KY kinetic kit 60 tests and (1) 500 ng CSE vial	291-53101-HS

Limulus PS Single Test

The Limulus PS Single Test is a kit composed of LAL endotoxin-specific reagent and an affinity resin suspension known as Pyrosep™, designed to overcome any product interference by adsorbing potential endotoxin in samples while washing away the inhibitory components.

Limulus PS Test	Packaging	Code
Limulus PS single test	20-test kit	299-54501-HS
PS accessory kit	1 kit	294-33311-HS

Accessories

Endotoxin Extracting	Packaging	Code
Endotoxin extracting solution	4 x 10 mL	293-51601-HS

Tube Reader Sterilized Consumables	Packaging	Code
BioClean® tip Wako 200 II	200 µL x 100 pcs	291-35021
BioClean® tip Wako 1000 II	1,000 µL x 100 pcs	298-35031
BioClean® tip Wako extend S II	200 µL x 100 pcs	294-35011
Limulus test tube, sterile w/aluminum cap (12 x 75 mm)	80 pcs	292-32751
Limulus test tube, sterile (12 x 75 mm)	100 pcs	293-26551
Aluminum cap, sterile (14.7 x 18 mm)	100 pcs	293-28251
13 x 100 mm dilution tubes	50 tubes/box	DL-13100
BioClean® 96 well microplate <0.01 EU/mL	50/box	293-35221
Toximaster® QC7 MPR software package		298-35391
10 x 75 mm pyrogen-free gel clot reaction tubes	200 tubes/case	CT-1075
10 x 75 mm pyrogen-free gel clot reaction tubes with aluminum caps	50 sets/case	CT-1075C

Control Standard Endotoxin	Packaging	Code
Control standard endotoxin, 500 ng	1 pack/6 vials	CSE4037-5006

Lysate Reagent Water	Packaging	Code
Lysate reagent water, 30 mL	20 x 30 mL	LRW-2030
Lysate reagent water, 100 mL	12 x 100 mL	LRW-12100

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.

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

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1.800.762.7016 | askcharlesriver@crl.com | www.criver.com

0.5 M $MgSO_4$ IN 1.0 M TRIS BUFFER SOLUTION (TRIS {HYDROXYMETHYL} AMINOMETHANE)

INTENDED USE:

The 0.5 M $MgSO_4$ in 1.0 M Tris Buffer Solution is used as an adjunct for endotoxin testing by Limulus Amebocyte Lysate (LAL) methods. The principle use of this solution is to provide divalent-cation replacement and pH buffering to test-materials prior to LAL testing.[1] The USP Bacterial Endotoxins Test <85> for LAL test applications allows the use of adjuncts to overcome inhibitory LAL-test conditions.[2]

EXPLANATION OF TEST:

The LAL test is the most sensitive and specific means available to detect and measure bacterial endotoxin. The LAL reaction is an enzyme mediated process which requires a neutral pH environment and a proper balance of monovalent and divalent cations.[1,2] A pH-related inhibition is likely when the pH is lower than the optimum range and when there is a failure to recover the positive product control (PPC) in the LAL test. If divalent cations in the LAL Reagent are depleted because of the presence of high concentrations of chelating agents, such as > 0.1 M citrate, there will be a failure to recover the PPC, as well. With the addition of magnesium sulfate and Tris buffer solution, the optimum reaction conditions for the LAL reaction may be restored.

The most common types of LAL-test interference are sub-optimum pH and divalent-cation depletion conditions.[1] The ideal method to resolve chemical inhibition is to use permissible dilution. When levels of interfering components in the test sample are high and the maximum valid dilution (MVD) is low, the use of additives are the only option to testing within the permissible dilution. See use instructions below.

COMPOSITION:

Each vial contains 4 mL of 0.5 M $MgSO_4$ in a pH-buffering solution containing a 1.0 Molar concentration of Tris (hydroxymethyl)-aminomethane with a pH of 6.8 to 7.6. The buffer is terminally sterilized and is endotoxin-free.

WARNINGS AND PRECAUTIONS:

1. For in vitro use only. Not to be used in humans or animals.
2. Only use this reagent for pH neutralization and Mg replacement of solutions being prepared for LAL test using Endosafe® LAL Reagent. Do not use this buffer to rehydrate Endosafe® LAL Reagent.
3. Do not use this reagent unless it is clear and colorless.
4. Only use pH electrodes that are compatible with Tris solutions.

0.5 M $MgSO_4$ IN 1.0 M TRIS BUFFER SOLUTION (TRIS {HYDROXYMETHYL} AMINOMETHANE)

STORAGE CONDITIONS: Store solution at room temperature. Do not freeze.

PROCEDURES:

Determination of the pH of the sample-LAL mixture.

1. Dilute the material to be tested to the desired concentration.
2. Mix equal parts of diluted test solution and Endosafe® LAL in a depyrogenated tube.
3. Check the pH of the mixture with a Tris-compatible system. The test material may be incompatible with LAL methods if the pH is not in the optimum range of 6.5 to 8.0.
4. Add suitable aliquots of this Mg/Tris solution to the test material until the LAL-sample mixture is in the optimum pH range and is compatible with the selected LAL method.

Routine LAL-test application.

1. If Mg replacement and pH adjustment are required for routine LAL testing, conduct a validation study to confirm the volume of Mg/Tris solution to be added per unit amount of test material.
2. Ideally, add the Mg/Tris solution during the first dilution step to maximize the effect of the magnesium-replacement buffer.
3. To test under conditions that are consistent with the USP Bacterial Endotoxins Test <85>[2], the pH must be measured and recorded for a routine LAL test which requires a pH-neutralized procedure.

REFERENCES:

1. Cooper, J.F. "Resolving LAL Test Interferences." J. Parent. Sci. & Tech., 44:1, p.13 (1990).
2. Bacterial endotoxins test <85>. In The U.S. Pharmacopeia, 37th rev., United Book Press Inc., Baltimore, MD.

Manufactured By: CHARLES RIVER ENDOSAFE
Div. of Charles River Laboratories, Inc.
1023 Wappoo Road, Suite 43B
Charleston, SC 29407, USA
PHONE NUMBER: 843-402-4900
FAX NUMBER: 843-766-7576

PIBC100001

0.25 M TRIS BASE SOLUTION (TRIS {HYDROXYMETHYL} AMINOMETHANE)

INTENDED USE:

The 0.25 M Tris Base Solution is used as an adjunct for endotoxin testing by Limulus Amebocyte Lysate (LAL) methods. The principle use of this solution is to buffer acidic solutions prior to LAL testing.[1] The USP Bacterial Endotoxins Test <85> for LAL test applications allows the use of adjuncts to overcome inhibitory LAL-test conditions.[2]

EXPLANATION OF TEST:

The LAL test is the most sensitive and specific means available to detect and measure bacterial endotoxin. The LAL reaction is an enzyme-mediated process which requires a neutral pH environment and a proper balance of monovalent and divalent cations.[1,2] A pH-related inhibition is likely when the pH is lower than the optimum range and when there is a failure to recover the positive product control in the LAL test. With the addition of the 0.25 M Tris Base Solution to an acidic test solution, the pH of the material may be brought to neutrality by a gradual process.

The most common type of LAL-test interference is sub-optimum pH conditions.[1] The ideal method to resolve pH-related interference is to use permissible dilution. Since the Endosafe® LAL Reagent is well buffered, neutralization of the test sample may not be needed after test-sample dilution, even though the material is known to be acidic, beforehand. However, when levels of interfering components in the test sample are high and the maximum valid dilution (MVD) is low, the use of additives is the only option to testing within the permissible dilution. Refer to the procedure section for proper use of the 0.25 M Tris Base Solution.

COMPOSITION:

Each vial contains 5 mL of a pH-buffering solution containing a 0.25 Molar concentration of Tris (hydroxymethyl) aminomethane with a pH of approximately 9. The buffer is terminally sterilized and is endotoxin-free.

WARNINGS AND PRECAUTIONS:

1. For in vitro use only. Not to be used in humans or animals.
2. Only use this reagent for pH neutralization of solutions being prepared for a LAL test using Endosafe® LAL Reagent. Do not use this buffer to rehydrate Endosafe® LAL Reagent.
3. Do not use this reagent unless it is clear and colorless.
4. Only use pH-measuring electrodes that are compatible with Tris solutions.

STORAGE CONDITIONS: Store solution at room temperature. Do not freeze.

0.25 M TRIS BASE SOLUTION (TRIS {HYDROXYMETHYL} AMINOMETHANE)

PROCEDURES:

Determination of the pH of the sample-LAL mixture.

1. Dilute the material to be tested to the desired concentration, within the MVD.
2. Mix equal parts of diluted test solution and Endosafe® LAL in a depyrogenated tube.
3. Check the pH of the mixture with a Tris-compatible system. The test material may be incompatible with LAL methods if the pH is not in the optimum range of 6.5 to 8.0.
4. Add suitable aliquots of the 0.25 M Tris Base Solution to the test material until the LAL-sample mixture is both in the optimum pH range and compatible with the selected LAL method.

Routine LAL-test application.

1. If pH adjustment is required for routine LAL testing, conduct a validation study to confirm the amount of 0.25 M Tris Base Solution to be added per unit amount of test material.
2. Ideally, add the 0.25 M Tris Base during the first dilution step to maximize the efficiency of the neutralization procedure. The combination of dilution and first-step buffering will minimize both the amount of required buffer and dilution of the test material.
3. To test under conditions that are consistent with the USP Bacterial Endotoxins Test <85>[2], the pH must be measured and recorded for a routine LAL test which requires a pH-neutralized procedure.
4. For raw materials such as strong organic acids or very acidic solutions, it may be necessary to dissolve or pre-treat the test material with 0.1 N NaOH before neutralization with 0.25 M Tris Buffer Solution.

REFERENCES:

1. Cooper, J.F. "Resolving LAL Test Interferences." J. Parent. Sci. & Tech., 44:1, p.13 (1990).
2. Bacterial endotoxins test <85>. In The U.S. Pharmacopeia, 37th rev., United Book Press Inc., Baltimore, MD.

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Charleston, SC 29407, USA
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PIBT10101

Endosafe® Control Standard Endotoxin

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Substance
Trade name	:	Endosafe® Control Standard Endotoxin
Chemical name	:	Lipopolysaccharides, escherichia coli
CAS-No.	:	93572-42-0
Product code	:	E110, E120, E170
Formula	:	Unspecified
Synonyms	:	Endotoxin, Lipopolysaccharides from Escherichia coli 055:B5 co-lyophilized in a stabilized medium, LPS, CSE, Endotoxin

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Scientific research and development

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Distributor: Charles River Laboratories Inc.

European Company Name: Charles River Microbial Solutions International Limited.

European Address: Unit 649 Greenogue Business Park,
Rathcoole,
D24 NF21,
Co. Dublin,
Ireland.

Phone number: 353 (0)1 506 9700 (site main number)

Email: endosafe-support@crl.com.

1.4. Emergency telephone number

Emergency number : 353 (0)1 506 9700 (site main number) Office hours 08:00 – 16:30 GMT Monday – Friday

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

other hazards which do not result in classification : Lipopolysaccharides are highly pyrogenic. Administered intravenously, the minimal pyrogenic dose in humans has been estimated at 4 ng/kg. Their toxicological properties have not been fully investigated.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%
Lipopolysaccharides, escherichia coli	(CAS-No.) 93572-42-0	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Move the affected person away from the contaminated area and into the fresh air.

First-aid measures after skin contact : Wash skin with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. If you feel unwell, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Symptoms/effects after skin contact : Not expected to present a significant skin hazard under anticipated conditions of normal use.

Symptoms/effects after eye contact : Not expected to present a significant eye contact hazard under anticipated conditions of normal use.

Symptoms/effects after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : On combustion forms: Carbon oxides (CO, CO2).

Explosion hazard : No direct explosion hazard.

5.3. Advice for firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire.

Protective equipment for firefighters : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Use personal protective equipment as required. For further information refer to section 8: "Exposure controls/personal protection".

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Avoid discharge to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Contain and collect as any solid.

Methods for cleaning up : Collect spillage. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Avoid dust formation. Rinse with water.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13 : "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure adequate ventilation.

Hygiene measures	:	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	:	Keep container closed when not in use.
Incompatible materials	:	Strong acids. Strong bases. Strong oxidizing agents.
Storage temperature	:	2 – 8 °C

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Not required for normal conditions of use.

Hand protection:

Impermeable protective gloves. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. EN 374

Eye protection:

Not required for normal conditions of use. Where contact with eyes or skin is likely, wear suitable protection

Respiratory protection:

No respiratory protection needed under normal use conditions

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Appearance	:	Powder.
Colour	:	White.
Odour	:	Odourless.
Odour threshold	:	No data available
pH	:	No data available
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Not flammable
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	Soluble.
Partition coefficient n-octanol/water (Log Pow)	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Do not expose to heat.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizing agents.

10.6. Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Lipopolysaccharides, *escherichia coli* (93572-42-0)	
LD50 oral rat	48300 µg/kg

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)
Other information : Likely routes of exposure: ingestion, inhalation, skin and eye.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : This material has not been tested for environmental effects.
Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid discharge to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not applicable	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not applicable	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not applicable	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not applicable	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not applicable	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not applicable

Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Lipopolysaccharides, *escherichia coli* is not on the REACH Candidate List

Lipopolysaccharides, *escherichia coli* is not on the REACH Annex XIV List

Lipopolysaccharides, *escherichia coli* is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 july 2012 concerning the export and import of hazardous chemicals.

Lipopolysaccharides, *escherichia coli* is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Germany

Water hazard class (WGK)	:	Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV)
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	The substance is not listed
SZW-lijst van mutagene stoffen	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	:	The substance is not listed

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

No additional information available

Charles River - SDS_EU_REACH_Annex_II - 200408

Endosafe® LAL Reagent Water

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Substance
Trade name	:	Endosafe® LAL Reagent Water
Chemical name	:	Water
CAS-No.	:	7732-18-5
Product code	:	W110, W120, W130, W150
Formula	:	H2O
Synonyms	:	AQUA / Aqua
REACH authorisation exemptions	:	Exempted from REACH registration

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Scientific research and development

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Distributor: Charles River Laboratories Inc.

European Company Name: Charles River Microbial Solutions International Limited.

European Address: Unit 649 Greenogue Business Park,
Rathcoole,
D24 NF21,
Co. Dublin,
Ireland.

Phone number: 353 (0)1 506 9700 (site main number)

Email: endosafe-support@crl.com.

1.4. Emergency telephone number

Emergency number : 353 (0)1 506 9700 (site main number) Office hours 08:00 – 16:30 GMT Monday – Friday

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%
Water	(CAS-No.) 7732-18-5	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	:	No special requirements.
First-aid measures after inhalation	:	None under normal use.
First-aid measures after skin contact	:	None under normal use.
First-aid measures after eye contact	:	None under normal use.
First-aid measures after ingestion	:	None under normal use.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Presents no particular fire or explosion hazard. Not flammable.

Explosion hazard : No direct explosion hazard.

5.3. Advice for firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire.

Protective equipment for firefighters : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No additional risk management measures required.

6.1.1. For non-emergency personnel

Protective equipment : Not required.

Emergency procedures : None reasonably foreseeable.

6.1.2. For emergency responders

Protective equipment : Not required.

Emergency procedures : None reasonably foreseeable.

6.2. Environmental precautions

No special environmental precautions required.

6.3. Methods and material for containment and cleaning up

For containment : Soak up with a cloth.

Methods for cleaning up : Absorb spillage to prevent material damage. No special decontamination procedures needed.

Other information : Spilled material may present a slipping hazard.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13 : "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : No special handling advices are necessary.

Hygiene measures : None reasonably foreseeable.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Protect from freezing.

Incompatible materials : Strong reducing agents. Acid chlorides. Phosphorus trichloride. Phosphorus pentachloride. Phosphorus oxychloride.

Storage temperature : 15 – 30 °C

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Not required for normal conditions of use. No special requirements.

Hand protection:

Not required

Eye protection:

Not required

Respiratory protection:

Not required

Other information:

None known.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Appearance	:	Clear.
Molecular mass	:	18.01 g/mol
Colour	:	Colourless.
Odour	:	Odourless.
Odour threshold	:	No data available
pH	:	6 ± 1.0 at 25 ºC
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	0 °C
Freezing point	:	0 °C
Boiling point	:	100 °C
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Not applicable
Vapour pressure	:	23.8 mm Hg (@ 25 °C)
Relative vapour density at 20 °C	:	No data available
Relative density	:	23 g/cm³ (@ 25 °C)
Density	:	0.997
Solubility	:	Soluble.
Partition coefficient n-octanol/water (Log Pow)	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	1 cP (@ 20 °C)
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Protect from freezing.

10.5. Incompatible materials

Strong reducing agents. Acid chlorides. Phosphorus trichloride. Phosphorus pentachloride. Phosphorus oxychloride.

10.6. Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	:	Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	:	Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	:	Not classified (Based on available data, the classification criteria are not met)

Water (7732-18-5)	
LD50 oral rat	> 90000 mg/kg

Skin corrosion/irritation	:	Not classified (Based on available data, the classification criteria are not met) pH: 6 ± 1.0 at 25 ºC
Serious eye damage/irritation	:	Not classified (Based on available data, the classification criteria are not met) pH: 6 ± 1.0 at 25 ºC
Respiratory or skin sensitisation	:	Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	:	Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	:	Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	:	Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	:	Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	:	Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	:	Not classified (Based on available data, the classification criteria are not met)
Other information	:	Likely routes of exposure: ingestion, inhalation, skin and eye.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	:	Presents no specific risk for the environment.
Hazardous to the aquatic environment, short-term (acute)	:	Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	:	Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : None

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations	:	No special requirements.
Ecology - waste materials	:	This product does not present any particular risk for the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Water is not on the REACH Candidate List

Water is not on the REACH Annex XIV List

Water is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 july 2012 concerning the export and import of hazardous chemicals.

Water is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

Listed on the AICS (Australian Inventory of Chemical Substances)

Listed on the Canadian DSL (Domestic Substances List)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on KECL/KECI (Korean Existing Chemicals Inventory)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Germany

Water hazard class (WGK)	:	Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV)
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	The substance is not listed
SZW-lijst van mutagene stoffen	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	:	The substance is not listed

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

No additional information available

Charles River - SDS_EU_REACH_Annex_II - 200408

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND COMPANY

Product Name LIMULUS AMEBOCYTE LYSATE (ENDOCHROME-K, KTA, KTA^2, LAL)
Brand Endosafe®
Product Codes R165, R11012, R11025, R12003, R12006, R12012, R12025, R13003, R13006, R13012, R13025, R13500, R13600, R15003, R15006, R15015, R160, R170, R19000, Bax100

Intended Use R&D/Experimental use only

Manufacturer Address Charles River Endosafe, a Division of Charles River Laboratories, Inc.
1023 Wappoo Road, Suite 43-B
Charleston, SC 29407
USA

Telephone 001 843 402 4900
Emergency 001 843 402 4900

SECTION 2: HAZARDS IDENTIFICATION

Classification Not a dangerous substance or mixture.

Label elements This product does not require labeling.

Hazard statements None

Other hazards None

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name Hemocyte, *Limulus polyphemus*, lysate (product consisting of the circulating amebocytes of *Limulus polyphemus* co-lyophilized in a buffered medium)

Other names Limulus Amebocyte Lysate, LAL

Components	CAS#	EC#	Concentration, %
Hemocyte, *Limulus polyphemus*, lysate	68606-22-4	271-731-2	< 80%
Proprietary formula components comprised of lyophilization fillers (salts, sugars, buffers)	–	–	> 20%

SECTION 4: FIRST AID MEASURES

Eye contact Flush eyes with plenty of water.

Skin contact Rinse immediately with soap and plenty of water.

Ingestion Never give anything by mouth to an unconscious person. Rinse mouth with water.

Inhalation Move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

SECTION 5: FIRE-FIGHTING MEASURES

Flash point	Not available
Ignition temperature	Not available
Extinguishing media	Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide.
Fire fighting procedures	Wear self contained breathing apparatus for fire fighting, if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions	Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.
Environmental precautions	Prevent product from entering drains.
Methods for cleaning	Use a wet sponge or damp cloth. Keep in suitable, closed containers for disposal.

SECTION 7: HANDLING AND STORAGE

Handling	Wear personal protective equipment, and avoid contact with skin and eyes. Good laboratory techniques should be used in handling product.
Storage	Recommended storage temperature: 2 - 8 °C.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering measures	Contains no substances with occupational exposure limit values.
Respiratory protection	Where risk assessment shows air-purifying respirators are appropriate, use a full-face respirator with multipurpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Eye protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin and body protection	Wear appropriate protective gloves and clothes to prevent skin exposure.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practices.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Powder, lyophilized
Odor	Not available
pH	Not available
Melting/freezing point	Not available
Boiling point	Not available
Flash point	Not available
Freezing point	Not available

Evaporation rate	Not available
Flammability	Not available
Upper/lower flammability limits	Not available
Vapor pressure	Not available
Vapor density	Not available
Specific gravity	Not available
Water solubility	Soluble
Partition coefficient: n-octanol/water	Not applicable
Decomposition temperature	Not available
Viscosity	Not applicable

SECTION 10: STABILITY AND REACTIVITY

Stability	Stable under recommended storage conditions
Materials to avoid	Strong acids, bases and oxidizers
Conditions to avoid	Heat
Hazardous polymerization	None under normal processing conditions
Hazardous decomposition	Hazardous decomposition products formed under fire conditions – Carbon oxides

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity	Not available
Skin corrosive/Irritant	Not available
Serious eye damage/irritation	Not available
Respiratory sensitization	Not available
Germ cell mutagenicity	Not available
Carcinogenicity	
IARC	No components of this product present at levels greater than or equal to 0.1% are identified as a probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity	Not available
Specific target organ toxicity (single exposure)	Not available
Specific target organ toxicity (repeated exposure)	Not available
Aspiration hazard	Not available

SECTION 12: ECOLOGICAL INFORMATION

Aquatic and terrestrial toxicity	Not available
Persistence/degradability	Not available
Bioaccumulative potential	Not available
Mobility in soil	Not available
Other adverse effects	Not available

SECTION 13: DISPOSAL CONSIDERATIONS

Product	Observe all federal, state, and local environmental regulations.
Contaminated packaging	Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

ADR/RID	Not dangerous goods
IMDG	Not dangerous goods
IATA	Not dangerous goods

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

No data available

SECTION 16: OTHER INFORMATION

Disclaimer

Although the information and recommendations set forth herein (hereinafter "information") are presented in good faith and believed to be correct as of the date hereof, Charles River Laboratories, Inc. makes no representations as to the completeness or accuracy thereof. Information is supplied upon the condition that the users will make their own determination as to its safety and suitability for their purposes prior to use. In no event will Charles River Laboratories, Inc. be responsible for damages of any nature whatsoever resulting from the use of or reliance upon information.

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Prepared by

Charles River Laboratories, Inc.
Phone: 001 843 402 4900
www.criver.com