

# Kinetic Endotoxin Testing Solutions



Charles River offers a complete portfolio of bacterial endotoxin testing reagents and technologies, including our innovative cartridge-based testing systems, to help you ensure safety in your manufacturing processes. Our kinetic turbidimetric reagents yield quantitative endotoxin values and feature

buffered formulations that provide robust testing with the highest accuracy and precision. Charles River kinetic solutions utilize FDA-licensed, compendial-compliant limulus amoebocyte lysate (LAL) and can be used with confidence for all your testing requirements, including end product release.

## Kinetic Chromogenic (KCA) LAL Reagents:

- Endosafe®-PTS™, featuring preloaded cartridge technology for rapid micromethod testing
- Endochrome-K™, with an optimized formulation that provides increased sensitivity, greater linearity and superior interference resistance (available in kit format or bulk packaging)

## Kinetic Turbidimetric (KTA) LAL Reagents:

- KTA, a traditional reagent suitable for both kinetic and gel-clot analysis and permitting a direct correlation between methods
- KTA<sup>2</sup>, a second-generation reagent for kinetic analysis, with a formulation that offers the performance of a kinetic chromogenic LAL reagent at a turbidimetric price

## Software Solutions:

- EndoScan-V™ endotoxin-specific software, compatible with a variety readers and consistent with FDA requirements

We also offer a full range of endotoxin-free accessories, including pipettes, tubes, reagent water, buffers and plates.



## Kinetic Chromogenic (KCA) LAL

### PTS™ Cartridges

The ultimate in simplicity and speed, Endosafe®-PTS™ cartridges offer a 15-minute endotoxin assay utilizing our FDA-licensed compendial-compliant kinetic chromogenic LAL testing solution. This proven, innovative technology delivers fully quantitative results in a rapid, easy to use, self-contained package, eliminating preparation of multiple reagents and reducing the opportunity for technician error. LAL testing has never been easier or less error-prone. Approved for use with all product types, including end product release, PTS™ cartridges are compatible with the portable test system (PTS™), multi-cartridge system (MCS™) and fully-automated Nexus™ system. The disposable cartridge contains four channels — two channels with CSE and LAL, which serve as the positive control channels, and two channels with LAL for testing of samples. To perform the test, simply add 25µl of sample into all four sample reservoirs. The reader's internal pump moves the sample along the channels' reagent stations for mixing, then into the optical cells of the cartridge to be read kinetically.

### Endochrome-K™

A fully quantitative and uniquely stable kinetic chromogenic reagent, Endochrome-K™ features an optimized KCA formulation that offers an unrivaled combination of sensitivity, linearity and interference resistance. Endochrome-K™ delivers quantitative endotoxin values in roughly an hour, and its use of reconstituted LAL allows for extended bench time and reuse, making it a highly cost-effective solution.



## Kinetic Turbidimetric (KTA) LAL

KTA is an FDA-licensed testing solution that yields quantitative endotoxin values in the same amount of time it takes to run a gel-clot assay, and usually less. Utilizing a buffered reagent that provides significant interference resistance, KTA is licensed for both kinetic and gel-clot analysis and permits direct correlation between the two methods.

### KTA<sup>2</sup>

A second generation kinetic turbidimetric reagent, KTA<sup>2</sup> offers faster reaction times over a wider standard curve range (to 0.005 EU/ml) than traditional KTA reagents. The superior formulation of KTA<sup>2</sup> delivers the performance of kinetic chromogenic reagents at turbidimetric prices. Like our KTA reagent, KTA<sup>2</sup> is FDA-licensed and buffered to provide significant interference resistance.

## LAL Accessory Products

Accurate results rely on robust reagents, but also on the right accessories. Charles River offers a comprehensive range of accessories to support you and enhance your confidence in the results of all your endotoxin testing methodologies. The range includes depyrogenated glass pipettes and tubes, LAL reagent water, LAL buffers and 96-well plates, as well as other high-quality accessories. All accessory products are provided with a certificate of quality certifying appropriate endotoxin levels.



## EndoScan-V™ Endotoxin-Specific Software

EndoScan-V™ is a fully validated and verified endotoxin-specific software package, and is compliant with FDA requirements. With flexible setup and intuitive data analysis, the software is compatible with a variety of microplate and tube readers, as well as the PTS™ and MCS™ cartridge readers and the Nexus™ fully-automated system. EndoScan-V™ features drag-and-drop capability for fast and easy template setup, a user-defined product database, flexible exporting functions and enhanced security features, and is available in English, French and German language versions.

## Endosafe® Microtrend

Tracking and trending is possible with our Endosafe® Microtrend database trending software. The software utilizes SQL (Structured Query Language) to track and trend LAL test data, as well as monitor the proficiency of laboratory analysts. Microtrend provides a tool to proactively identify endotoxin excursions along with the availability to easily access reports to support out-of-specification (OOS) investigations.

## BioTek Plate Readers and Support

Our partnership with BioTek allows for a superior level of support for BioTek plate readers. In addition to selling the BioTek ELX808IU™ reader, the Charles River technical support team qualifies the instrument for compatibility with Endoscan-V™ software and the LAL test. This service provides a smooth transition for replacing or implementing a BioTek plate reader for BET testing. Our onsite annual qualification of the BioTek reader and software provide the assurance that the plate reader is operating correctly and fulfills the preventative maintenance requirements recommended by Charles River.



## The Charles River Kinetic Testing Solutions Portfolio\*

Kinetic Chromogenic (KCA) LAL	
PTS™	FDA-licensed, USP- and Ph. Eur-compliant LAL test cartridges
	Ultimate in simplicity and speed
	Prevents bottlenecks and hold steps
	Improves sample management and reduces technician errors
	Available in 4 sensitivity ranges:
	- 0.5 - 0.005 EU/ml
	- 1.0 - 0.01 EU/ml
	- 5.0 - 0.05 EU/ml
Endochrome-K™	32 tests per 3.2 ml vial
	Can test to 0.001 EU/ml using the appropriate conditions
	Licensed for linear and polynomial regression
	Buffered interference-resistant reagent
	Highly stable reagent available in kit form or bulk packaging
Kinetic Turbidimetric (KTA) LAL	
KTA	50 Tests per 5.2 ml vial
	50 - 0.015 EU/ml standard curve range (using the appropriate conditions)
	Can be used for kinetic and gel-clot analysis
	Buffered interference-resistant reagent
KTA <sup>2</sup>	50 Tests per 5.2 ml vial
	Can test to 0.005 EU/ml using the appropriate conditions
	Licensed for linear and polynomial regression
	Buffered interference-resistant reagent
Kinetic chromogenic performance at turbidimetric prices	
Software	
EndoScan-V™ (ESV)	Validated endotoxin-specific software
	Enhanced security and audit trail feature
	Drag-and-drop for fast and easy template setup
	Save and reuse templates for improved efficiency
	Full qualification package available
	Available in English, French and German
Accessories	
	Depyrogenated endotoxin-free pipettes, tubes and sampling material
	LAL reagent water
	LAL buffers
	96-well polystyrene plates

\* Please contact Customer Service for details.