charles river

Endosafe® Cartridge Technology

How endotoxin testing should be done

Twenty years ago

the bacterial endotoxin test was radically transformed.

Analysts, who manually created standard curves and waited for LAL results, yearned for a more robust assay that delivered faster quantitative results in real-time.

Our scientists envisioned streamlining benches cluttered with vials and pipettes by creating an automated, simplified method to eliminate labor-intensive endotoxin testing.

Since its introduction in 2003, Endosafe cartridge technology has replaced the need for traditional gel-clot and plate-based methods with a more reliable, compendial, and easier-to-use solution.

In 2006, traveling over 220 miles above Earth's surface at a speed of 17,500 mph, the Endosafe PTS and LAL cartridge was utilized to perform biological studies necessary for an extended human presence in space on the International Space Station.

Endotoxin Testing Made Easy

Rapid. Simple. Seamless.

Now, with Endosafe cartridges, any user can generate rapid, automated BET results in about 15 minutes by loading a cartridge into our instruments and pipetting 25 µL of sample into four wells.

Results ready in approximately 15 minutes.

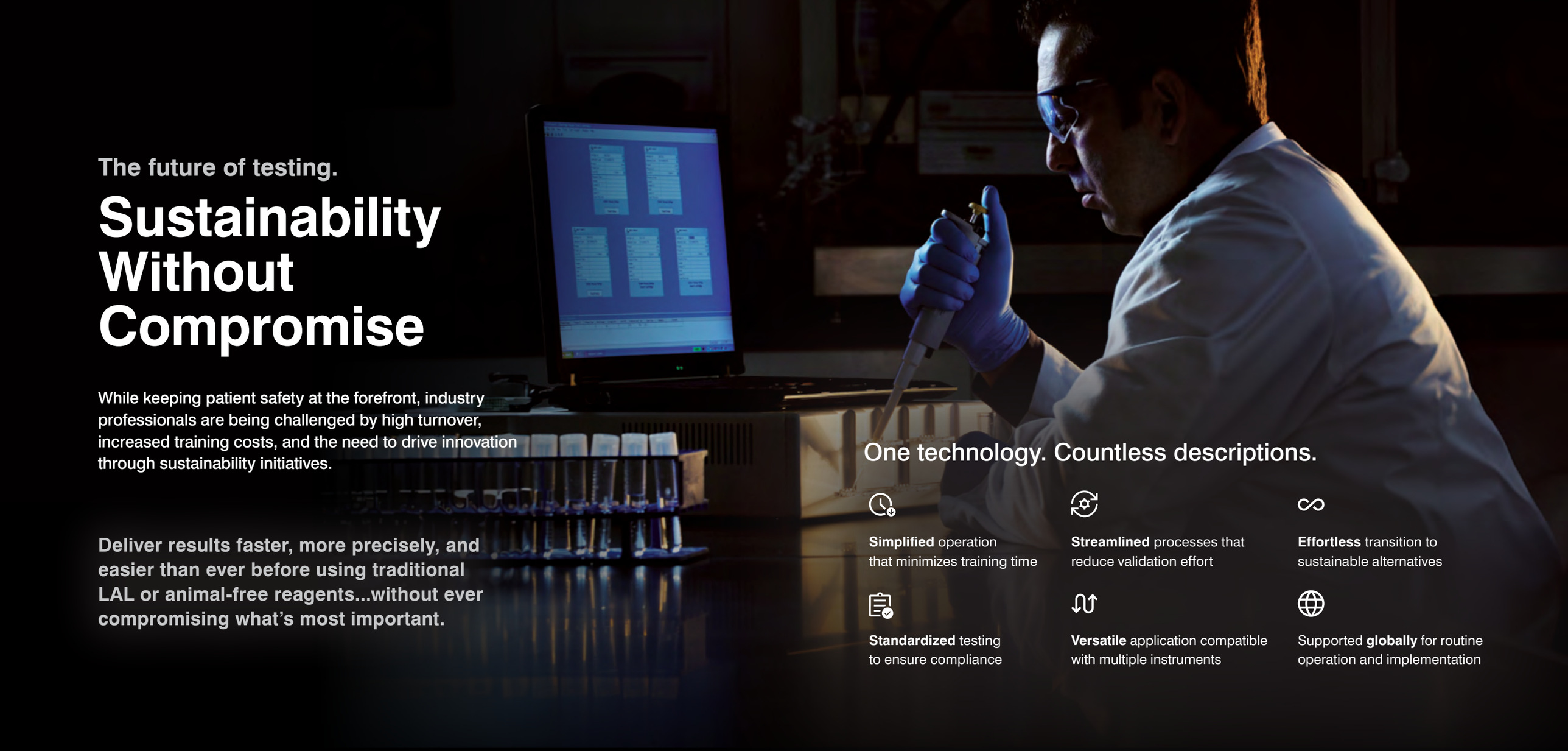
Duplicate sample and PPC meet harmonized pharmacopeia requirements for endotoxin tests

Change in optical density is interpolated against the archived standard curve quantifying to the level of endotoxins

Endosafe cartridges automate chromogenic reaction and incubation processes

Pumps draw and mix samples and reagents, then move to the optical cell for analysis

Instant on-screen results, no further interpretation required



The future of testing.

Sustainability Without Compromise

While keeping patient safety at the forefront, industry professionals are being challenged by high turnover, increased training costs, and the need to drive innovation through sustainability initiatives.

Deliver results faster, more precisely, and easier than ever before using traditional LAL or animal-free reagents...without ever compromising what's most important.

One technology. Countless descriptions.

Simplified operation that minimizes training time

Streamlined processes that reduce validation effort

Effortless transition to sustainable alternatives

Standardized testing to ensure compliance

Versatile application compatible with multiple instruments

Supported **globally** for routine operation and implementation

Endosafe® LAL Cartridges

The trusted solution that set the standard.

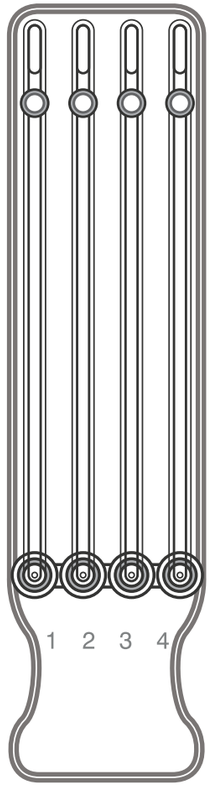
For over two decades, LAL cartridges have delivered peace of mind across multiple industries. As a compendial-based method, implementing cartridges is simple, delivering the highest sensitivity while using 95% less horseshoe crab material than traditional LAL, gel-clot, and turbidimetric methods. It's no wonder why it's become the go-to solution for routine BET.

What makes these cartridges the industry standard?

Approximately 15-minute kinetic chromogenic LAL results boost efficiency

FDA-licensed LAL cartridges ensure regulatory compliance since 2006

Uses archived standard curve to minimize human error



Quantitative ranges, 0.5 to 0.005 EU/mL, 1 to 0.01 EU/mL, 5 to 0.05 EU/mL, 10 to 0.1 EU/mL

Reduces manual steps, reagent and glass waste, and costs, minimizing environmental impact

Compatible with Endoscan-V™ for streamlined endotoxin data management

Endosafe® Trillium™ rCR Cartridges

Sustainable by design, with flexibility in mind.

Never before has it been easier to implement a routine, animal-free, sustainable solution. Endosafe® Trillium™ recombinant cascade reagent (rCR) cartridges, powered by a full 3-Factor enzymatic cascade, replicate the natural Limulus reaction. Fully compatible with existing Endosafe instruments and software, Trillium cartridges deliver all the same benefits while simultaneously driving commitment to the 3Rs (Replace, Reduce, and Refine).

The Trillium Difference

Simplified workflows minimize error with fewer steps than other recombinant options

Available in quantitative ranges 1 to 0.01 EU/mL, 5 to 0.05 EU/mL

Delivers quicker results compared to any other recombinant methods and boosts operational efficiency

Cuts glassware and eliminates reagent waste furthering sustainability efforts

Wide quantitative range meets diverse sample testing needs

Archived standard curves in rCR reduce errors and increase reliability

Eliminates false positives that can be caused by Beta-Glucans, enhancing result integrity

Industry Accepted. Regulatory Approved.

With over 20 million cartridges manufactured, it is currently utilized for raw material, in-process, and final release testing across thousands of products worldwide.

Since receiving its FDA license in 2006, Endosafe LAL Cartridges have been widely adopted as a kinetic chromogenic method aligned with USP <85>, and Ph. Eur. 2.6.14. Holding an FDA Biologics License Application (BLA) license means we are held to the same standards that you or any other biologics manufacturer are expected to adhere to, and ensure the quality and safety of our products.

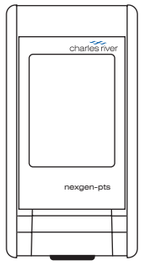
Approved for use in testing the following product applications

- Pharmaceutical products
- Biologicals
- Nuclear medicine samples
- Dialysis samples
- Pharmaceutical water systems
- Stem cell materials
- Cleaning validations
- Medical devices
- Compounded products

One Cartridge. Three Robust Platforms.

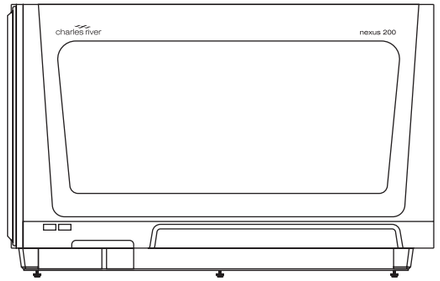
Extensive cross-compatibility to meet your needs.

All cartridges are compatible with nexgen-PTS™, nexgen-MCS™, and Nexus 200™, allowing for enhanced testing versatility, integration, and scalability. This compatibility reduces equipment needs and streamlines processes, boosting efficiency and cutting costs.



Endosafe® nexgen-PTS™

Endosafe® nexgen-MCS™



Endosafe® Nexus 200™

Scalable integration through our suite of instruments

Endosafe® nexgen-PTS™

for point-of-sample testing

- Handheld spectrophotometer: portable, suitable for at-line testing
- Quickly analyze rush samples and raw materials
- Real-time data analysis with enhanced reporting features
- Secured with password protection and FDA-compliant user management
- Glove compatible, easy touchscreen operation

Endosafe® nexgen-MCS™

for higher sample throughput

- Stackable benchtop system analyzes multiple cartridges simultaneously in approximately 15 minutes
- Independent sample runs eliminate batch sampling necessity
- EndoScan-V calculates endotoxin levels and assay acceptance criteria

---

Endosafe® Nexus 200™

for fully automated testing

- Fully automated walkaway robotic system
- Up to 120 diluted or undiluted samples per run
- Bar-coding technology enhances accuracy, reducing data management errors
- Enhances data integrity with full audit trail, minimizing regulatory non-compliance risks
- Powered by EndoScan-V software allowing for LIMS integration and improved traceability, security, and data management

Quality Controlled for Your Quality Control

The Archived Standard Curve (ASC)

Each batch of cartridges including FDA licensed LAL-cartridges features a pre-established standard curve, analyzed via regression for specific endotoxin concentrations, significantly reducing preparation time, variability, and uncertainty commonly associated with other BET. Each lot is rigorously tested for accuracy and precision, accompanied by a unique calibration code and Certificate of Analysis, ensuring high confidence and reliability in your daily BET consumables.

Beta-Glucan Cartridges

The Beta-glucan assay is a rapid, in-process test designed for investigational purposes to ensure that products do not contain (1,3)-β-D glucans. Glucans are known to cause false-positive results in LAL assays, which could trigger an investigation.

Beta-Glucan Cartridges Specifications

Sensitivity range of 10-1,000 µg/mL

Results in approximately 30 minutes

Measures color intensity in a kinetic method, similar to LAL assays

Our commitment to conservation doesn’t stop.

Protecting the Atlantic horseshoe crab.

We have a responsibility to preserve, protect, and live harmoniously with the animals that share our planet.

As your trusted partner, we shoulder the responsibility of providing sustainable solutions that align with global initiatives and bolster your own sustainability endeavors. That’s why we have developed a comprehensive portfolio of bacterial endotoxin testing solutions that serve your specific needs while simultaneously embracing patient safety and a sustainable future. With the release of Trillium, we’ll continue our advocacy and protection of *Limulus* species.

Reducing Horseshoe Crab Raw Material Usage

Gel-Clot LAL

0%
reduction
Kinetic Turbidimetric LAL*

54%
reduction
Kinetic Chromogenic LAL*

95%
reduction
LAL Cartridge Technology*

100%
replacement
Recombinant Cascade Reagent (rCR)*

*Compared to Gel-Clot LAL

charles river

Access our catalog and implement any of our sustainable offerings from our industry-leading Endosafe portfolio.

Learn why over 5,000 organizations have adopted this rapid and compendial technology to streamline their manufacturing processes.

Get more information at criver.com/endosafe

Connect with us

USA: +1.877.274.8371
International toll free: +800.3195.3430
askcharlesriver@crl.com