VEOLIA

The Essential Buyer's Guide for the **Sievers Eclipse Automated Endotoxin Testing Platform**

The Essential Buyer's Guide for **the Sievers* Eclipse BET Platform**

Despite the need for easier, automated, and more sustainable solutions for bacterial endotoxins testing (BET), it's difficult to find consolidated information about practical and compliant technologies that are available today to simplify this critical assay.

To address this problem, the Sievers team has put all this information in one place to help you make informed purchasing decisions as you switch to an automated endotoxin testing platform.

In this comprehensive Buyer's Guide, you'll learn:

- The five biggest pain points in endotoxin testing today
- How the Sievers Eclipse BET platform works
- Ten factors to consider before implementing an automated platform
- How the Sievers Eclipse directly compares to other technologies (including 96-well plates, gel clot, cartridges, and robotics)
- Seven ways the Sievers team supports you through the onboarding process
- The eight biggest benefits of switching to the Eclipse

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The Top Five Pain Points in Endotoxin Testing Today

If you conduct endotoxin testing, you know that traditional assay setup leaves a lot to be desired. Below are the five most common challenges talked about in endotoxin testing:

1. Efficiency & Ergonomics

Drug manufacturers need QC instrument suppliers to continually innovate to improve efficiencies that allow more scalability— with minimal hands-on time. Industry 4.0 calls for automation and real-time data, driving the future of endotoxin testing away from conventional labor-intensive methods -- that often have higher retest rates -- to streamlined technologies that reduce the time and cost it takes to release drug products to patients.

Improved efficiency in endotoxin testing also results in improved ergonomics. Traditional BET methods require standard curve preparation, which includes pipetting steps. Reducing the amount of pipetting reduces the impact on an analyst's health and safety.

2. Sustainability

Traditional Limulus amebocyte lysate (LAL) test methods, which include the 96-well plate and gel clot, utilize much more LAL reagent than microfluidic platforms. A typical full run of samples will use as much as 10mL of reagent, which is both costly and places higher demand on the horseshoe crab, the blood from which LAL is created.

In addition to minimizing the amount of LAL needed per run, modern endotoxin testing technologies can minimize cold storage and eliminate storage needs for reference standard endotoxin (RSE) or control standard endotoxin (CSE), thus reducing costs and simplifying the supply chain.

Resources for endotoxin testing extend beyond reagents and storage to include the sustainability of workers. To that end, minimizing unnecessary repetitive actions for lab personnel is a high priority in labs today – one supported by implementing automated technologies to protect employee health and wellness.

The Top Five Pain Points in Endotoxin Testing Today

3. Installation & Validation

Automated technologies and robotics are needed to operate more efficiently, but some tools require complex installations and/or validation processes, which make them harder to adopt. Streamlining the installation and validation processes can mean the analyst is up and running faster, ultimately leading to faster release of drug products to the market.

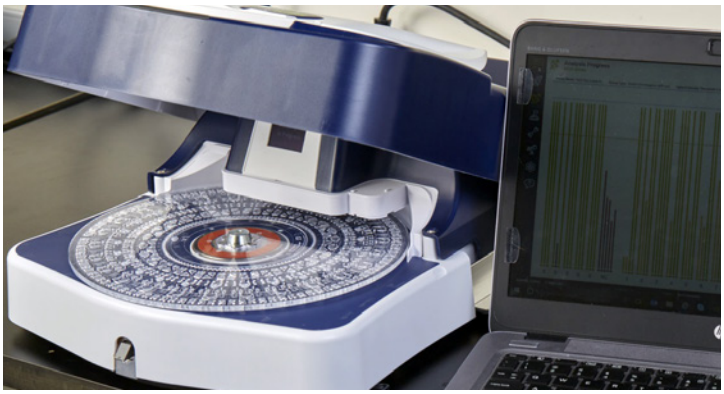
4. Data

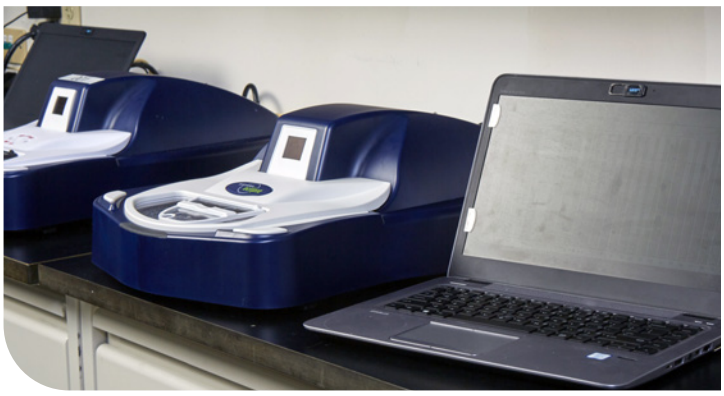
Customers need easier, faster, and more consistent and reliable data that meet all compendial and data integrity requirements. Labs desire remote and customizable data management, review, and sign off while ensuring data integrity.

5. Compliance

Not all robotic liquid handling systems prepare a standard curve or include negative controls. Compendia require both to ensure every assay has controls and accounts for any technician, environment, or reagent variability from assay to assay. Even if you're not deploying robotics, traditional methods may fall short of today's needs. For example, gel clot methods lack many common data integrity features, such as an audit trail, which can be a major pain point within a quality driven organization.

We knew there was a better way to simplify bacterial endotoxin testing. So, we created the Sievers Eclipse BET Platform.





The easiest path to simple, fast bacterial endotoxin testing (BET) is using an integrated, plug-and-play platform that is purpose-built for endotoxin automation. Ease of use, hands-on time, environmental contamination, compliance, and software are all addressed to simplify automation.

Introducing The Sievers Eclipse BET Platform.

- Set up a 21-sample assay in **as little as nine minutes**
- Use up to **90% less LAL** and minimize supply chain dependencies
- Achieve full compliance with **21 CFR Part 11 and ALCOA+**
- Installation and validation takes as little as **two days**

10 Things to Think About as You Implement Simplified Endotoxin Automation

Making the switch to a different testing platform is a significant move, so it's crucial to make an informed decision to select the right automation solution for you. Here are 10 factors to consider before implementing a new endotoxin automation platform:

- Consider the ultimate goals of your lab and organization to help choose the right automated technology for you. Common objectives include maximizing sample throughput, reducing LAL usage, minimizing hands-on time and training, and ensuring regulatory compliance.
- Determine which pathways you may want to take or avoid. For example, choosing a compact benchtop analyzer to implement automation vs validating a robotic system; staying with the same kinetic method vs switching methods (chromogenic/turbidimetric); or changing to testing only water with a new method vs testing water and all products.
- Understand how successful BET automation can positively impact various departments in your facility, not just the QC lab.
- Ensure method suitability and comparability of a new testing platform.
- Beware the potential pitfalls of complex system validation and avoid them.
- Use vendor support as needed for validation and training. Aim to perform validation and training in tandem and within a few days.
- Rely on the simplicity and efficiency of assay setup on your new automated platform to make steps easier, such as performing bridge studies and method development. Partner with suppliers to further simplify these steps.
- Remember software's role in simplification and be sure to take advantage of time-saving templates and libraries.
- Use enterprise software for easy, remote data management.
- Never compromise on data integrity or compliance.

The Sievers Eclipse Vs. Other Endotoxin Testing Platforms

	ROBOTIC PLATFORM WITH 96-WELL PLATE READER	ROBOTIC PLATFORM WITH CARTRIDGE READER	MULTIPLE CARTRIDGE READER	96-WELL PLATE READER	MICROFLUIDIC AUTOMATION PLATFORM – SIEVERS ECLIPSE
	Robotic liquid handling is integrated with traditional 96-well plates to pipette LAL reagents, control standard endotoxin/reference standard endotoxin (CSE/ RSE), and samples.	A liquid handling robot is paired with LAL cartridge technology. Cartridges contain LAL reagent, chromogenic substrate, and CSE.	This multi-cartridge system uses LAL-cartridge technology to run one sample per cartridge. LAL reagent, chromogenic substrate, and CSE are contained within disposable cartridges.	Performing traditional LAL assays with 96-well microplates requires a high volume of pipetting and is time consuming and prone to errors. Standards and samples must be prepared, and lysate must be reconstituted prior to addition.	Microfluidic automation minimizes pipetting and mixing steps without the use of robotics. This microplate-based platform uses embedded RSE with centrifugal microfluidics to automate standard curves, PPCs, and mixing. Minimal LAL reagent is required.
TECHNOLOGY	Robotic liquid handling, plate based	Robotic liquid handling, cartridge based	Cartridge based	Manual pipetting	Automated microfluidic liquid handling
STANDARD CURVE AUTOMATION	Yes. Robotic dilution of CSE/RSE.	No. Archived standard curve. CSE embedded.	No. Archived standard curve. CSE embedded.	No. Manual pipetting of CSE dilutions.	Yes. RSE embedded.
HANDS-ON TIME	●○○○○ Robotic deck layout and script	●○○○○ Robotic deck preparation and cartridge loading	●●○○○ Individual sample loading and pipetting	●●●●● No robotics, extensive manual pipetting	●○○○○ No robotics, minimal pipetting
LAL USAGE	●●●●●	●○○○○	●○○○○	●●●○○	●○○○○
SAMPLE THROUGHPUT	●●●●○	●●●●○	●●○○○	●●○○○	●●●●●
COMPLIANT ENTERPRISE SOFTWARE	✓	✓	✓	✓	✓
VALIDATION CONSIDERATIONS	Robotics and standard IQ, OQ, PQ	Robotics, cartridge hold time study, and standard IQ, OQ, PQ	Standard IQ, OQ, PQ	Standard IQ, OQ, PQ	Standard IQ, OQ, PQ
FOOTPRINT IN LAB	●●●●●	●●●○○	●○○○○	●○○○○	●○○○○

Based on average 8-hour shift using a single platform.

3 Easy Ways to Switch to the Eclipse

1. Kinetic Chromogenic	**Kinetic Chromogenic on Eclipse**

- Most direct transition with biochemistry remaining consistent by maintaining the 1:1 sample to lysate ratio
- Once the system is validated, it is recommended to complete a bridge study
- 1 lot verification at the validated dilution is justifiable when utilizing the same kinetic method

2. Kinetic Turbidimetric	**Kinetic Chromogenic**

- Perform method suitability to compare inhibition/enhancement to the turbidimetric method and demonstrate adequate recovery of endotoxin with the chromogenic method
- It is recommended to perform a three-lot revalidation for final validated product testing

3. Gel-clot	**Kinetic Chromogenic**

- Perform method suitability as described above
- It is recommended to perform a three-lot revalidation for final validated product testing

The team behind Sievers Eclipse offers extensive support to help you throughout the implementation process.

We offer an IQ/OQ/PQ Validation Support Package (VSP) to comprehensively validate the system

Our Certified Sales Engineers assist in the validation process

Our Specific Software Protocol assists in Product Validation

We help you switch methods
(ex: Kinetic Turbidimetric → Kinetic Chromogenic)

We offer a bridge study protocol to assist in bridging from your current kinetic chromogenic platform to the Eclipse platform

Our comparability protocol executes a comparison study between the Sievers automated platform and the 96-well plate platform

The Sievers team performs a full platform validation report

Conclusion:

It's time to feel good about endotoxin testing. These are just 8 of the biggest benefits our customers rave about after implementing the Sievers Eclipse BET Platform:

Fast, easy setup with full compliance to USP <85>, EP 2.6.14 and JP 4.01

Reduced opportunity for contamination and errors

Significant reduction in LAL usage

PPCs prepared for you

Standard curve and negative controls are automated

Improved operational efficiency

21 CFR Part 11 and ALCOA + compliant software that is easy to navigate and fully customizable with permissions and assay templates

Simplified training

Schedule a demo today to see how your lab can benefit from the Sievers Eclipse.

https://www.watertechnologies.com/lp-ai-eclipse-demo