Sievers Eclipse*

compliant, consistent, conscious bacterial endotoxins testing

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suez

SIEVERS eclipse

SUEZ, through its Sievers product line of analytical instruments and technologies, introduces the **next revolution in endotoxin detection.**

The Sievers Eclipse* Bacterial Endotoxins Testing (BET) Platform empowers users to be conscious of today's needs to protect valuable natural resources while still complying with the strict analytical and regulatory requirements drug and device manufacturers must meet.

By decreasing horseshoe crab (HSC) lysate use by up to 90%, the Eclipse platform reduces the demand on the most sensitive and unmatched natural endotoxin detection reagent on the planet. It delivers a fully compliant BET assay that the global HSC population can sustain. The Sievers Eclipse BET platform decreases setup time by up to 85% while meeting all USP, EP, and JP compendial requirements. Through innovative design, the Eclipse platform significantly decreases pipetting steps, reduces operator-to-operator variability, and simplifies assay setup.

The benefits:

Save on lysate usage, reduce time to results, and increase sample throughput without sacrificing accuracy or regulatory compliance.

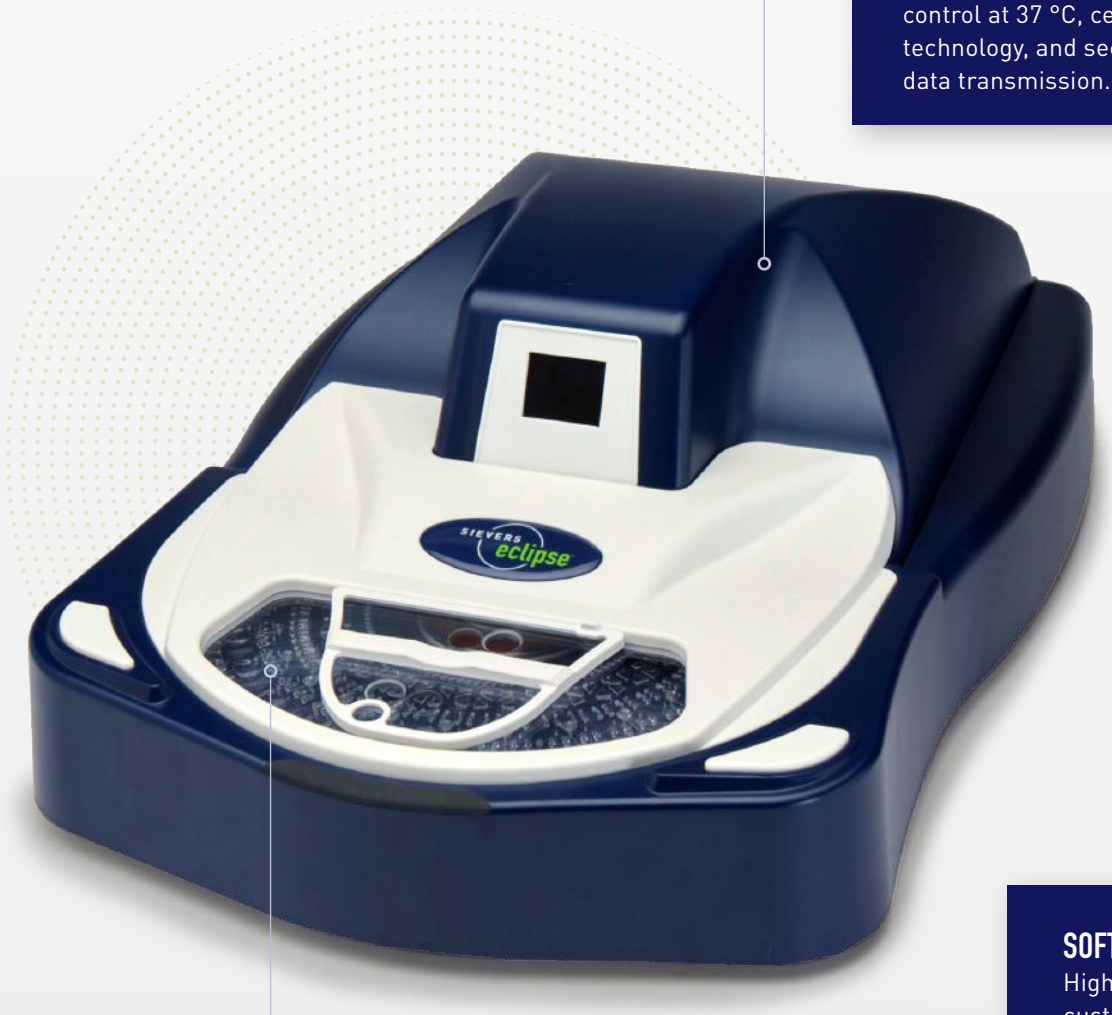
up to

85%

decrease in setup time while meeting all USP, EP, and JP compendial requirements.

The Sievers Eclipse platform delivers a fully compliant BET assay that the global HSC population can sustain.

ANALYZER
Absorbance analyzer with consistent incubation control at 37 °C, centrifugal technology, and secure data transmission.



MICROPLATE
Precise liquid handling device that achieves automation through innovative microfluidic technology with embedded endotoxin standards and PPCs.

SOFTWARE
Highly customizable enterprise solution with 21 CFR Part 11 and ALCOA+ Data Integrity compliance features.

do more with less when less is more

Reduce LAL reagent use by up to 90%

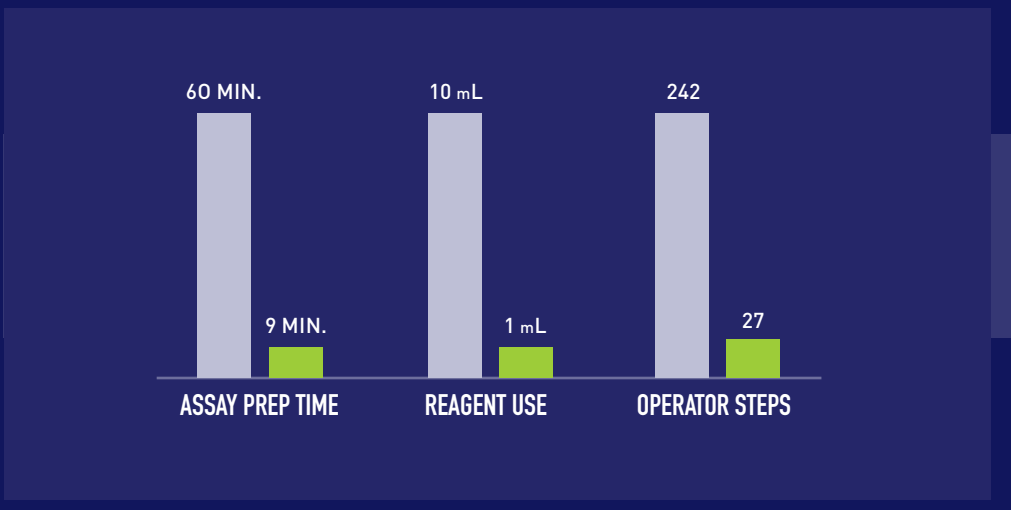
Increase daily sample throughput

Reduce prep time by up to 85% and set up assays in as little as 9 minutes

Meet global regulatory requirements

Reduce pipetting steps by up to 89% and decrease the risk of repetitive stress injury

Maintain compliance with 21 CFR Part 11 and Data Integrity guidelines



The Sievers Eclipse BET platform delivers in four key areas:

Regulatory Compliance

The Eclipse platform consists of three components - an analyzer, microplate, and software - and is designed for quality control testing of water and drug product within the pharmaceutical, medical device, and hemodialysis markets. The platform uses commercially available, FDA licensed Limulus Amoebocyte Lysate (LAL) from the major LAL manufacturers and meets all requirements of the harmonized global pharmacopoeia (USP <85>, EP 2.6.14 and JP 4.01). The Eclipse platform enables manufacturers to maintain their ability to run 21 samples per assay, with a sensitivity down to 0.005 EU/mL. The platform combines automated technology with the kinetic chromogenic method to deliver regulatory compliance with unmatched performance and efficiency.

Simplification

The Eclipse platform dramatically streamlines assay setup and saves time with deposited Reference Standard Endotoxin (RSE) derived standards and Positive Product Controls (PPCs). This results in an up to 89% reduction in pipetting steps and a decreased risk of repetitive stress injury.

Analytical Performance

The patented Sievers Eclipse microplate delivers robust analytical performance with precise microfluidic technology. This technology delivers automation through embedded endotoxin standards and PPCs in conjunction with consistent liquid handling. The outcome is accurate results with a decreased risk of error and contamination.

Increased Efficiency

This system drastically increases laboratory efficiency by reducing labor by up to 85% and expensive LAL reagent use by up to 90%. With technology-driven precision and fewer steps, the Eclipse platform decreases the need for extensive operator training and the risk of repetitive stress injury while increasing the number of assays manufacturers can perform in one day.

up to **89%** reduction in pipetting steps and a decreased risk of repetitive stress injury.

up to **85%** reduction in labor.

up to **90%** reduction in LAL reagent use.

The Eclipse microplate is a precision-crafted microfluidic liquid handling device designed to significantly streamline kinetic chromogenic assays for the detection of bacterial endotoxins. This groundbreaking microplate delivers the ability to run a fully compliant endotoxin assay while maintaining throughput of 21 samples per plate.

THE ECLIPSE MICROPLATE, in conjunction with the Eclipse analyzer and software, uses centrifugal force and pneumatic chambers to measure and evenly distribute precise amounts of LAL reagent water, samples, and LAL across 104 optical wells.

THE 104 OPTICAL WELLS comprise 26 segments:

- 5 standard curve segments for the option to run a 3-, 4-, or 5-point standard curve in triplicate. These segments are pre-deposited with RSE from 50-0.005 EU/mL. Each of these segments contains a negative control well.
- 21 Sample Segments to run samples and 0.5 EU/mL PPCs in duplicate.

TO ENSURE THE LAL/ENDOTOXIN REACTION takes place at 37 ±1 ˚C, the Sievers Eclipse analyzer uses infrared temperature monitors that are NIST traceable to measure the exact temperature of the microplate throughout the test, an industry first.

Sievers Innovation

Get started

1 **TO GET STARTED,** the analyst pipettes 55 µL of LAL reagent water in each of the standard curve segments, then 55 µL of each sample into the remaining 21 segments. The user has the option to pre-incubate the samples and standards if required by the LAL manufacturer's instructions for use. Once all samples are added, 1.0 mL of LAL reagent is added to the center of the plate, for a total of 27 pipetting steps, and the assay is started.

2 **THE MICROPLATE ROTATES** to automatically distribute LAL and samples into individual metering chambers, which pressurizes specifically designed pneumatic chambers. The microplate then slows down, removing the forces of gravitational weight on the pneumatic chambers and forcing both LAL and sample against their gradients to meet in the optical well in an exact 1:1 ratio for mixing.

3 **THE UNIQUE MIXING PROCESS** of pre-deposited RSE, LAL reagent, and sample uses the proprietary motion and technology of the Sievers Eclipse platform to completely mix the solution. Once the solution is homogeneous, each optical well is read at 405 nm every five seconds, resulting in high definition view of each individual reaction.

Combining innovative design and precise microfluidics enables assay setup in 27 pipetting steps in as little as 9 minutes using up to 90% less lysate.

27
PIPETTING STEPS

AS LITTLE AS
9
MINUTE SETUP

UP TO
90%
LESS LYSATE USED

Specifications

System Specifications		
BET Method	Kinetic chromogenic	
Detection Mode	Absorbance	
Range	0.005–50 EU/mL	
Precision	≤ 15% CV onset time	
Accuracy	50–200% of actual	
Sample Type	Aqueous, injected by pipette	
Calibration	Up to 12 months	
Analysis Time	Up to 2 hours	
Sample Temperature	37 ± 1 °C	
Ambient Temperature	17–30 °C	
Capacity	Up to 21 samples in duplicate with positive product controls	
Temperature Control	37 ± 0.5 °C	
Light Source	LED emitter	
Fluidic Failure Detection	1450 nm emitter	
Optical Accuracy	≤ 5% deviation from expected value	
Optical Linearity	R-Value ≥ 0.980	
Optical Wavelength Filter	405 nm	
Read Interval	5 seconds	
Analyzer Specifications		
Outputs	Digital via USB	
Display	OLED	
Power Requirement	100–240 Volts AC @50/60 Hz	
Fuses	T 8 A 250 VAC Fuse, size 5 x 20 mm. ONLY Littelfuse 218008 or Cooper Bussmann S506-8-R.	
Dimensions	H: 17.5 cm (6.9 in); W: 35.1 cm (13.8 in); D: 50.3 cm (19.8 in)	
Weight	10 kg (22.1 lbs)	
Safety Certifications	UL 61010-1:2012Ed.3+R:20Apr2016 CSA C22.2#61010-1-12:2012Ed.3+U1;U2 UL 61010-2-010:2015Ed.3 UL 61010-2-020:2016Ed.3 CSA C22.2#61010-2-010:2015Ed.3	CSA C22.2#61010-2-020 IEC 61010-1:2010 Ed.3+C1;C2 IEC 61010-2-010:2003Ed.2 IEC 61010-2-020:2016Ed.3
Environment		
Maximum Relative Humidity	85%, non-condensing	
Maximum Altitude	3,000 m (9,800 ft)	
Pollution Degree	2	

Find a contact near you by visiting www.suezwatertechnologies.com/ai-request-more-information

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