



Sievers Eclipse\*

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## What is Microfluidic Automation of Bacterial Endotoxin Testing

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# What is Microfluidic Automation of Endotoxin Testing?

## The Clear Answer to Making BET Quick and Efficient

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Manual bacterial endotoxin testing (BET) is notoriously a tedious and inefficient process that is time and labor intensive and prone to human error and costly retests.

In contrast, the Sievers Eclipse platform uses microfluidic automation to make endotoxin testing faster, more efficient, and more sustainable without the need for complex robotics and without sacrificing accuracy or compliance.

**But what exactly is microfluidic automation and how does it work?**





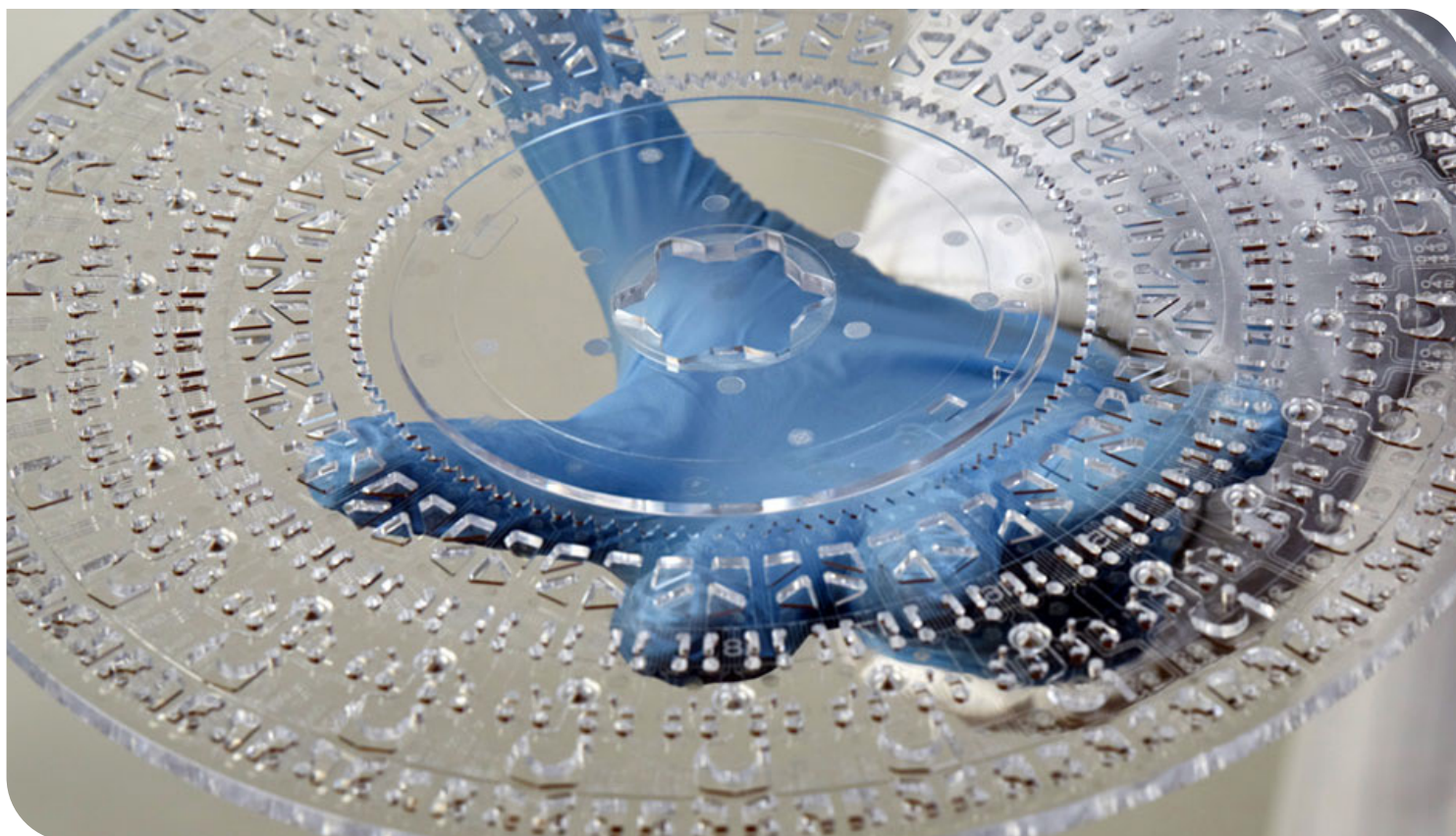
### **BET the old way with manual test set up**

- Requires hundreds of pipetting steps to set up a standard 96-well plate
- Can take an hour or more to start each assay
- Puts technicians at risk for repetitive motion injuries
- Is prone to errors due to high volume pipetting and operator-to-operator variability, which can lead to costly retesting
- Uses more LAL reagent, which is expensive and puts higher demand on natural resources

## **BET Using Microfluidic Automation with the Sievers Eclipse.**

### **What sets the Sievers Eclipse apart?**

- Microfluidic automation is achieved with a compact microplate that is analyzed using an incubating benchtop spectrophotometer that is similar in size and function to absorbance microplate readers that are used for traditional LAL assays.
- The Sievers Eclipse platform uses embedded endotoxin standards and PPCs in conjunction with consistent microfluidic liquid handling to automate kinetic chromogenic assays without compromising compliance.
- All the end users must do is load LAL Reagent Water and samples onto the plate with no additional prep work. Then 1 mL of LAL reagent is added, and the assay is started.
- It precisely manipulates smaller reaction volumes than traditional assays, which reduces consumption of reagents and samples, cost, and set up time.
- The small benchtop platform requires less than 30 pipetting steps for a 21-sample test, which can be set up in as little as 9 minutes. This means you can run four 21-sample assays a day, saving hours of valuable time versus traditional testing.
- The microplate contains embedded endotoxin for a minimum 3-point standard curve in duplicate for each sample.
- Just 1 milliliter of LAL reagent is used for 21 samples, providing up to a 90% reduction in LAL reagent. This reduces the demand on valuable natural resources and delivers a fully compliant BET assay that the global horseshoe crab population can sustain.



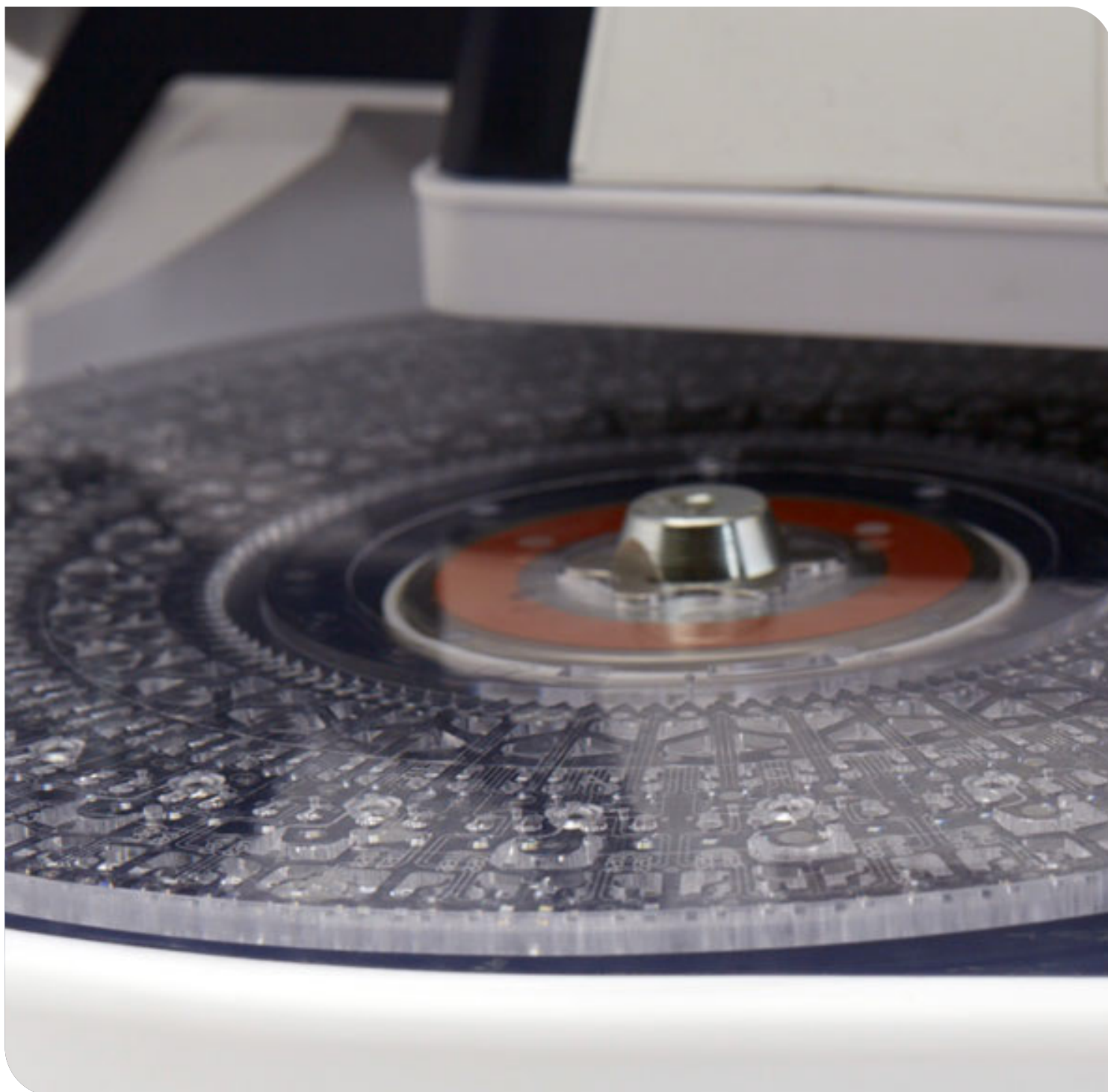
## Liquid Handling with the Eclipse Microplate

- Once the analyst starts microfluidic automation handles all the tedious work: measuring, mixing with LAL, and providing continuous readings throughout the assay.
- The microplate rotates and centripetal microfluidic automation will build and release pressure to disperse the fluids evenly through channels in the microplate. Liquid measurement, flow, and mixing are automated in preparation for analysis.
- Continuous motion ensures that a homogenous mixture of sample and reagent is maintained.



## The Result: Accurate Test Results and Secure Data Management

- Easy training and fewer manual setup steps mean less opportunity for human error or inconsistencies and allows a user to start testing faster.
- Reduced costs associated with reagent use and retesting due to errors.
- The Sievers Eclipse is fully compliant with all pharmacopeia compendial requirements, including USP <85> EP 2.6.14 and JP 4.01.
- The enterprise software solution conforms to 21 CFR Part 11 and ALCOA+ data integrity guidelines.



## Fully Compliant BET Assay

### Standard Curve

- Pre-deposited RSE directly from USP
- Options for 3-, 4-, or 5-point standard curve from 50-.005 EU/mL, in triplicate

### PPCs

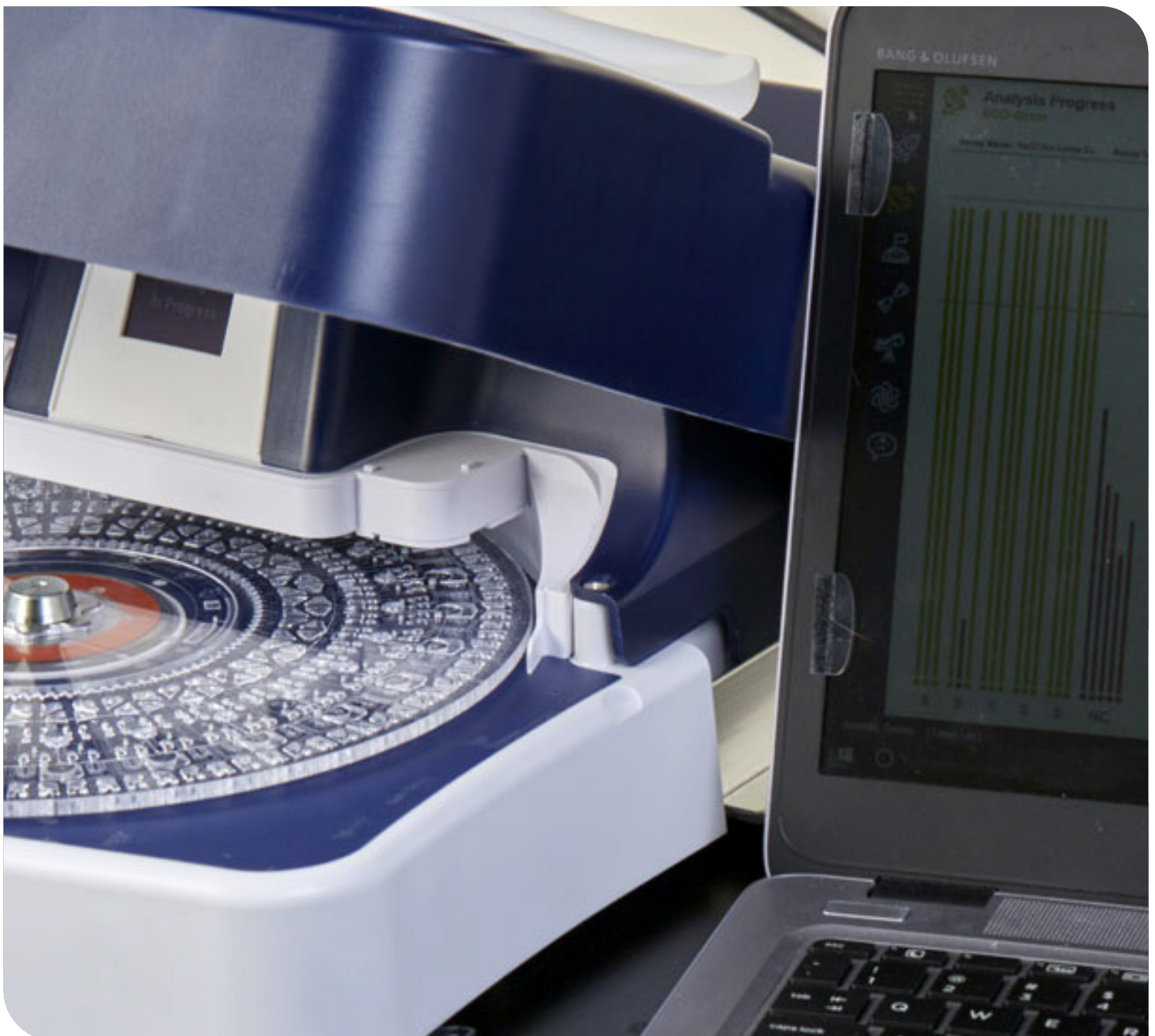
- Run in duplicate

### LAL

- Uses FDA-licensed LAL, just 1 mL per 21 samples
- Lysate qualification in at least triplicate

### Samples

- Run in duplicate, up to 21 samples per microplate





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