BIOMÉRIEUX

ENHANCING ENDOTOXIN TESTING PRECISION FOR CELL & GENE THERAPY

Embrace Automation with ENDOLISA®

Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS

The Complexities of Endotoxin Testing in Cell and Gene Therapy.

In the rapidly advancing field of Cell and Gene Therapy, ensuring the safety and efficacy of your products is key. Endotoxin testing can be challenging due to the unique qualities of these therapies:

Complex Biological Matrices

Your products involve sophisticated compositions, from viral vectors to living cells, creating environments where the recovery of endotoxins can be difficult.

Risk of Inaccurate Results

Our workflow with minimal hands-on time reduces the need for extensive expertise and training to get an objective, rapid, and accurate result. This allows you to decentralize your lab testing and move it closer to the manufacturing suite.

Regulatory Scrutiny

New regulations have been written specifically to support the use of rapid methods for use on products with short shelf lives such as advanced cell therapies. bioMérieux offers full validation support and technical staff to back you every step of the way.

Did you know?

Complex matrices is a recognized challenge for endotoxin testing in Cell and Gene Therapy. This can compromise the accuracy of results, leading to significant challenges in ensuring product safety and compliance.

Our ENDOLISA® solution, coupled with the ASSIST PLUS pipetting system from INTEGRA®, is designed to address these complexities, ensuring reliable results even with difficult matrices.

ENDOLISA® on ASSIST PLUS, a Tailored Solution for your Unique Needs

At bioMérieux, we understand the specific challenges you face in endotoxin testing for Cell and Gene Therapies. That's why we've developed a solution that directly addresses these pain points:

- Less human error
- Decreased invalid results
- More reproducibility

ENDOLISA® Assay

Unlike traditional methods, ENDOLISA® includes a unique washing step that removes interfering substances, providing accurate and reliable endotoxin detection even in complex matrices. This ensures that your results are both specific and sensitive, reducing the risk of false positives or negatives.

ASSIST PLUS Semi-Automated Pipetting System by INTEGRA®

By integrating ENDOLISA® with the ASSIST PLUS system, we've automated the most critical steps of the assay. This integration enhances the precision of the washing process and the consistency of the results.

Streamlined Workflow

Save time and reduce errors

- No separate incubator necessary
- No plate transfer necessary

Scalable and Flexible

Adapt easily to your demands and requirements

- Fully automated and hands-free washing steps

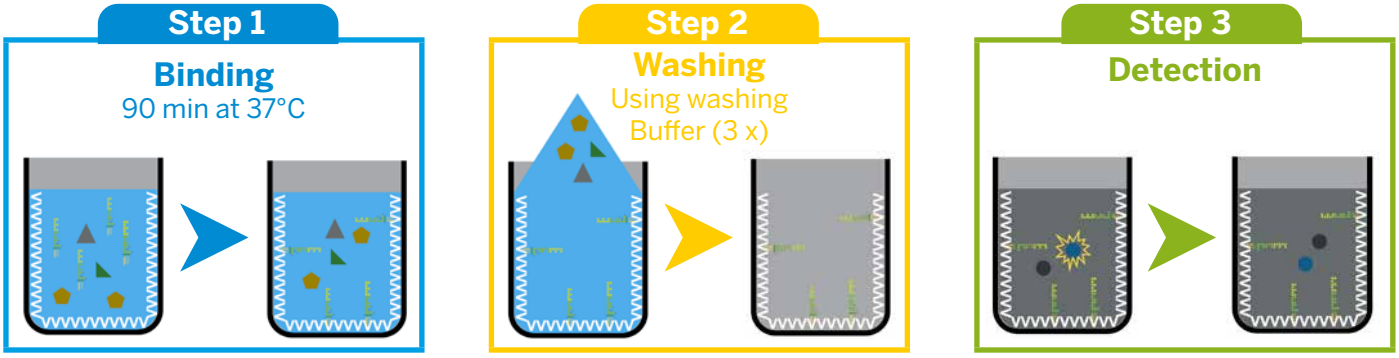
Unmatched Accuracy

Overcome matrix interference with confidence:

- Less human error
- More reproducible results

How Does it Work?

ENDOLISA® is a game changer in endotoxin testing of complex samples with a unique built-in sample preparation in 3 steps:



ENDOLISA® Semi-Automation Package for 1 to 6 Samples

- Automated plate filling
- Automated and clean washing
- Automated sample preparation possible
- Automated standard curve preparation possible

Test your Matrix - Ensure Feasibility with our ENDOXPERTS™ Support

We know that every product is unique, and some matrices can be particularly challenging. That's why we offer a feasibility testing service. Send us your samples, and our experts will work with you to determine if the ENDOLISA® assay is the right fit for your specific matrix.

- **Customized support: work with our technical team to optimize the assay for your unique needs.**
- **Feasibility testing: get a detailed report on how ENDOLISA® performs with your samples, so you can proceed with confidence.**
- **Tailored solutions: if challenges are identified, we'll help you find the best path forward,**

Ready to Enhance your Endotoxin Testing?

Contact us today to learn more about how ENDOLISA® on ASSIST PLUS can streamline your testing process, improve accuracy, and helps ensure compliance in your Cell and Gene Therapy products.

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