

BIOMÉRIEUX

# ENDONEXT™

The Evolution  
of Endotoxin testing



Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS

# Better for your lab. Better for the planet.

ENDONEXT™ endotoxin detection assays from bioMérieux are ushering in a new era of smarter, more sustainable pharmaceutical quality control.

Based on Recombinant Horseshoe Crab Factor C (rFC), ENDONEXT™ technology not only eliminates the need to harvest horseshoe crab blood—it makes your entire lab more efficient. With 100% endotoxin specificity, lot-to-lot consistency, and more streamlined workflows, ENDONEXT™ provides reliable results everywhere from in-process controls to final product testing on the most challenging matrices.

## ENDONEXT™ at a glance

- Sustainable rFC without using horseshoe crabs
- 100% endotoxin specificity—no false positives from β-Glucan
- Recombinant production provides high lot-to-lot consistency
- Fluorescence end-point assays in 96-well microplate format
- Validated according to standard pharmacopoeial Bacterial Endotoxin Testing criteria
- Solution for low number of sample decreasing plastic waste in the lab

### The ENDONEXT endotoxin testing range offers a solution for each application

APPLICATION	ENDOZYME® II • Flexible format	ENDOZYME® II GO • Fast workflow	ENDOZYME® II GO STRIPS • Fast and flexible	ENDOLISA® • Complex samples
In-process control of water & raw materials	✓	✓+	✓	✓+
Formulation & research	✓+	✓	✓+	✓
Final product	✓+	✓+	✓+	✓+
Sample interfering/ invalid with LAL				✓+
Low endotoxin recovery <sup>a</sup>	✓	✓	✓	
Cell and Gene Therapy				✓+
High-throughput		✓+		✓+
Small sample batch <sup>a</sup>			✓+	

✓ Suitable

✓+ Highly suitable

<sup>a</sup>When combined with dedicated sample preparation applying the ENDO-RS® method by bioMérieux.

## ENDOZYME® II

The enhanced second generation of ENDOZYME® is a flexible and easy-to-use endotoxin detection assay.

- State-of-the-art sensitivity down to 0.001 EU/mL
- Flexible assay time depending on required sensitivity
- Particularly suited for final product testing, formulation and research



## ENDOZYME® II GO

The rapid GO version of ENDOZYME® II featuring GOPLATE™—a microplate pre-filled with required standard curve and positive product control concentrations (PPC).

- Eliminates manual preparation of standard dilutions and PPCs
- Over 50% reduction in handling time compared to conventional microplate assays
- Significantly reduces risk of error
- Ideal for in-process control of water and raw materials as well as product release testing
- Easy automation
- The easiest, most rapid and versatile rFC assay kit on the market



>50% reduction of handling time



Minimized error rate



Down to 15 min assay time for in-process control of water



## ENDOZYME® II GO STRIPS

An extension of the prefilled GOPLATE™ line, on top of all the benefits describes above STRIPS line allow the flexibility to test anywhere from 1 to 21 samples with minimal waste.

## ENDOLISA®

With its unique built-in sample preparation step, the ENDOLISA® assay revolutionizes endotoxin testing of complex samples.

- ELISA-like format features 96-well plate pre-coated with a specific endotoxin-binding phage protein
- Overcomes limits of traditional methods such as inhibition and enhancement
- Unprecedented tolerance of organic solvents, detergents, and chaotropic agents
- Low to no dilution of samples



For complex matrices



Highly robust method





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## The People

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With more than 50 years' experience in microbiological diagnostics, the people of bioMérieux understand the challenges manufacturers face when it comes to ensuring product safety and quality. Our development, scientific affairs, customer service, and support teams work hand-in-hand with our clients to create and implement groundbreaking solutions to everyday problems.

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## The Products

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- ENDOZYME® II
  - ENDOZYME® II GO
  - ENDOZYME® II GO STRIPS
  - ENDOLISA®
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## The Science

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bioMérieux's cohesive range of innovative solutions help make pharmaceutical quality control more precise and efficient than ever. bioMérieux products not only enable faster, more accurate testing, but can also optimize lab workflow, boost productivity, and improve financial performance.