BIOMÉRIEUX

ENDOZYME® II GO

Endotoxin Testing made Faster, Easier, and Sustainable.

Your Ally in Advancing Quality

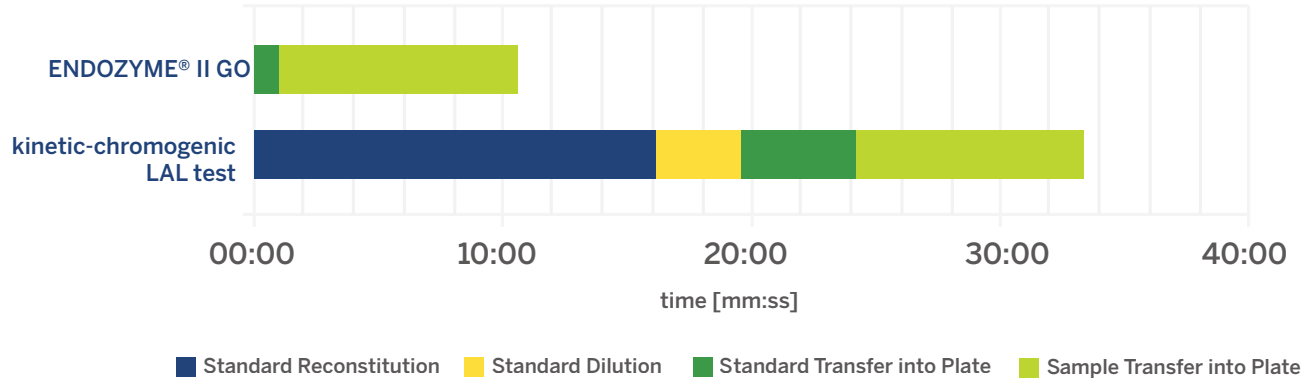
PIONEERING DIAGNOSTICS

Decreasing the handling factor to improve testing efficiency and reduce human error.

By significantly reducing hands-on time, ENDOZYME® II GO not only makes your lab more efficient—it reduces the risk of invalid results and reduces laboratory waste by eliminating manual preparation steps that are prone to handling errors.

Thanks to its 96-well pre-filled GOPLATE™, the ENDOZYME® II GO recombinant factor C (rFC) endotoxin detection assay eliminates the need for any vortexing, mixing, diluting, or adding of Control Standard Endotoxin (CSE) to achieve the standard curve and PPC's.

Streamline your Workflow with reduced Hands-on Time.*



WORKFLOW COMPARISON	LAL test	ENDOZYME® II GO
Standard Reconstitution	Required	**Not Required**
Standard preparation / Dilution	Required	**Not Required**
Standard & PPC Addition	Required	**Not Required**
Sample Addition	Required	Required
Reagent Preparation	Required	Required
Addition of Reagent	Required	Required

Lot-to-lot Reproducibility with Recombinant Scientific Characterisation.**

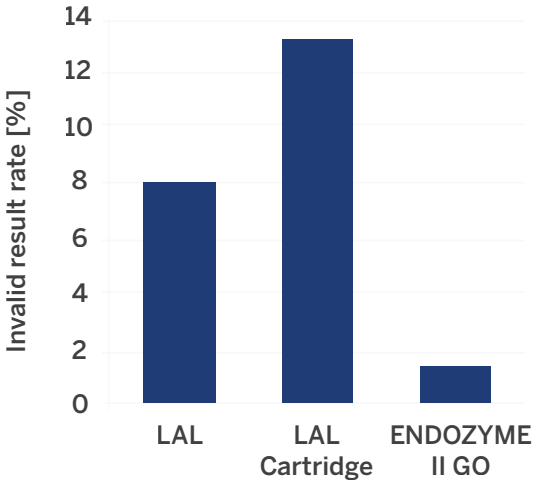
The rFC in ENDOZYME® II GO consists of a single recombinant protein and a small fluorescent peptide. This protein content can be measured to perfection and thus certifies no lot variability when using ENDOZYME® II GO. Therefore you can ensure the reproducibility of your internal quality control results batch after batch.

Optimize testing Costs with fewer invalid Results.***

Invalid results—and the resulting need to investigate and re-test—cost your lab both time and money. The GOPLATE™ pre-filled standard curve and positive product controls significantly reduce the rate of invalid results when using ENDOZYME® II GO, making your testing more efficient and more cost-effective.

Rate of invalid results

Invalid results in %.



100% Endotoxin Specificity. No False Positives.**

The rFC-based assay in ENDOZYME® II GO contains no Factor G pathway, the biosensor for ß-glucan that can cause false positives in LAL-based endotoxin testing—even when using ß-glucan blocking buffer. By removing the potential for false-positive results caused by ß-glucan, the rFC test with immediate, ENDOZYME® II GO provides straightforward, consistent results and eliminates the need for lengthy and costly testing ***.

* Data on file

** Microcoat Biotechnologie GmbH, "Study for Validation of Recombinant Factor C Reagent (ENDOZYME® II GO) as Alternative Method Compared to Limulus Amebocyte Lysate," 2019, showing rFC specificity to avoid beta glucan related false positive.

*** Comparison of bacterial endotoxin testing methods in purified pharmaceutical water matrices, Marine Marius

Striving for Sustainability and the three Rs.

The recent decade has seen a rapid acceleration and focus on sustainability initiatives, which has been one of the most significant transformational changes in the pharmaceutical industry.

Pharmaceutical manufacturers are looking at ways to cut waste, reduce their impact on the environment, and guarantee the supply of raw materials and resources. By switching from conventional to alternative endotoxin testing techniques for product release testing, there is an opportunity to reduce reagent waste, generate cost savings and comply with the three Rs principle (Replace, Reduce, and Refine). When Russell and Burch proposed the principles of Replacement, Reduction, and Refinement in 1959, they called the eventual replacement of animal-based research, education, and testing the "ultimate goal".[1]

By using recombinant Factor C technology, ENDOZYME® II GO is able to directly replace the LAL assay which requires bleeding of live animals—a practice estimated to cause 70,000 animal deaths annually in the USA alone.[2]

Legislative & Regulatory Responsibility.

The EU first introduced legislation protecting animals used for experimental or other scientific purposes in 1986, and updated it in 2010.

Directive 2010/63/EU on the protection of animals used for scientific purposes spells out the principles of Replacement, Reduction, and Refinement—and makes systematic consideration of these principles a firm legal requirement when animals are used for scientific purposes in the EU.[3]

ENDOZYME® II GO satisfies all these criteria and helps manufacturers «doing the right thing».

1. Russell, W. M. S., Burch, R. L.. 1959. The Principles of Humane Experimental Technique. London, UK: Methuen.

2. Atlantic States Marine Fisheries Commission (2016). 2016 Review of the Atlantic States Marine Fisheries Commission Fisheries Management Plan for Horseshoe Crab (Limulus polyphems) 2015 Fishing Year. Washington, DC.

3. https://ec.europa.eu/

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