PLA 3.0

# bioMérieux Endotoxin Detection Assay Package

PLA 3.0

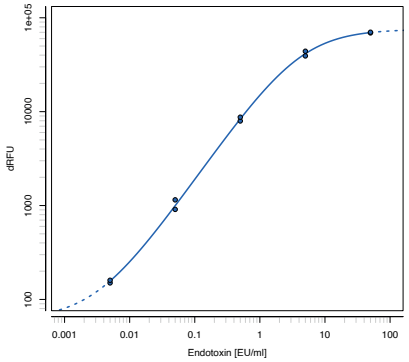
## UNLOCK THE POWER OF ENDOTOXIN ANALYSIS

Analyze the endotoxin concentration in a substance

Analyze the endotoxin concentration in a substance. Use our bioMérieux Endotoxin Detection Assay Package* to analyze the bioMérieux assay kits EndoLISA® and ENDOZYME® II GO. Simplify your reporting process by effortlessly creating professional PDF reports. Additionally, take advantage of our data export capabilities for external data processing.

Effortlessly streamline your assay analyzing process with intuitive configuration options and adjustable templates. Use our state-of-the-art software to accurately fit linear or 4-parameter logistic models to your reference standard, enabling precise calculations of assay sample activity and spike recovery from positive product controls. Easily optimize instrument sensitivity by calculating ideal amplification while ensuring assay validity through comprehensive testing of regression parameters, recovery, coefficient of variation, and blank control development. Seamless documentation of instrument settings and operator information for a smooth and efficient workflow are a given.

**Use our Tecan MagellanTM Import Module for bioMérieux Endotoxin Assays to conveniently import data into PLA 3.0. Read more at page 3.*




Standard curve of the 4-parameter logistic model

## FEATURES

– Analysis of endotoxin concentrationSetup of endotoxin limits

– Validity assessment via spiked samplesLinear and 4-parameter logistic models

– Adjustment of instrument sensitivity (gain optimization)

– Predefined assay templates for bioMérieux test kits

– Configurable assay layout and test systemDocumentation options about the operator and instrument

– PDF and CSV reports

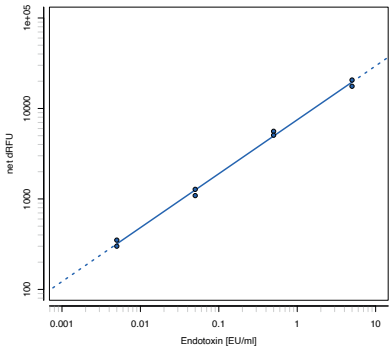
## BASIC CONCEPT

The bioMérieux Endotoxin Detection Assay Package is based on the bioMérieux methodology for calculating endotoxin concentration in samples. This includes support for all types of assay systems, extensive documentation options, statistical features such as weighted regressions, optimal gain of the instrument, and a configurable test system combined into a single PLA 3.0 document. You can define any number of test samples, their endotoxin limit and the spike amount of the related positive product control. Select either the linear or 4-parameter logistic

model as fit for your reference standard. Then provide measurements from the first and final time point. Interpolation analysis estimates the endotoxin level in test samples and the amount of recovered spike material for a thorough identification of valid or invalid samples. A configurable test system further checks for the validity of the assay.

## USE CASES

Endotoxins are part of the cell membrane from gram-negative bacteria. When released into a host organism after cell decay, endotoxins can cause serious pyrogenic effects. Detecting the amount of endotoxin in pharmaceutical products, which enter the human bloodstream, is therefore a mandatory step performed by laboratories. The bioMérieux endotoxin detection assay document provides all necessary tools to analyze endotoxin concentration as suggested by bioMérieux. The add-on comes with templates to support the 96-well test kits ENDOZYME® II (Go) and ENDOLISA® from bioMérieux. You can also define custom assay templates to use with your own assay configuration. Choose between linear and non-linear regression models to fit data of your reference standard. Prepare test samples by adding information about the threshold value of endotoxin concentration or the spike of the respective positive product control (PPC). Further add blank controls to use them as the baseline for the linear model approach and to determine assay validity. Results show the activity of test samples in relation to the reference standard, and the recovery rate of spiked PPCs. Assess the validity of your assay with configurable tests on regression parameters, PPC recovery rate, blank control development, or the variation in estimated endotoxin concentration. The bioMérieux endotoxin detection assay document also allows for the calculation of the optimum gain to qualify plate reader sensitivity. Create print-ready PDF reports or use the CSV format for further processing.




Standard curve of the linear model

## TECAN MAGELLAN™ IMPORT MODULE FOR BIOMÉRIEUX ENDOTOXIN DETECTION ASSAYS

Our solution connects to the Tecan Magellan™ plate reader software, and enables seamless integration of the resulting data for optimized analysis. Import initial and final plate readings from Tecan Magellan™ for use with bioMérieux endotoxin detection assays. This importer generates and calculates assay documents in PLA 3.0 automatically. Data integrity is our top priority. Every imported record can therefore be accurately tracked in the audit trail, ensuring total traceability and giving you peace of mind.

Direct data import from Tecan plate reader

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