



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

CHARLES RIVER ENDOTOXIN MICROBIAL DETECTION EUROPE SAS

9 Allée moulin berger

Ecully, France 69130

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BIOLOGICAL

Valid To: January 31, 2021

Certificate Number: 4123.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following types of tests:

On unknown bacterial and fungal samples:

<u>Test</u>	<u>Test Method(s)</u>
Genotypic Based Microbial Identification Using DNA Sequencing	In-House Method (NEW SOP-00116 and NEW-SOP-00123)
Proteotypic Based Microbial Identification Using Mass Spectrometry	In-House Method (NEW SOP-00117)

On pharmaceutical products, water or similar, medical devices, dialysis products and various containers (for packaging of endotoxin-free products – depyrogenation validation):

<u>Test</u>	<u>Test Method(s)</u>
Bacterial Endotoxin - Kinetic Chromogenic, Rapid Micro Method, Cartridges Technology	USP Ch. 85; EU Ch. 2.6.14 Described in PR14/INS/1397
Bacterial Endotoxin Test - Gel Clot	USP Ch. 85; EU Ch. 2.6.14 Described in PR14/INS/0753
Bacterial Endotoxin Test - Kinetic Chromogenic	USP Ch. 85; EU Ch. 2.6.14 Described in PR14/INS/0180
Bacterial Endotoxin Test - Kinetic Turbimetric	USP Ch. 85; EU Ch. 2.6.14 Described in PR14/INS/0180



## *Accredited Laboratory*

A2LA has accredited

# **CHARLES RIVER ENDOTOXIN MICROBIAL DETECTION EUROPE SAS**

*Ecully, FRANCE*

for technical competence in the field of

## **Biological Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



Presented this 22<sup>nd</sup> day of January 2019.

A blue ink signature of the Senior Director of Accreditation Services.

Senior Director, Accreditation Services  
For the Accreditation Council  
Certificate Number 4123.02  
Valid to January 31, 2021

*For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.*