

QC

Certificate of Analysis

REQUESTED BY: Hunter Scientific Limited (Unit 1, Priors Hall Widdington, Saffron Walden CB11 3SB Essex United Kingdom of Great Britain and Northern Ireland)

ASSAY REQUESTED BY CUSTOMER: LAL - Limulus amebocyte lysate assay

INTERNAL NUMBER: LAL.016.1250.2021
DATE: 30/06/2021 - 30/06/2021

DESCRIPTION OF TEST PRODUCT: Soda Pasteur Pipette
REF: PPS
LOT NUMBER: 5036
EXP. DATE: 2025-06

PROTOCOL:

Samples were fully loaded and exposed for 60 min to pre-warmed endotoxin-free water. Afterwards, the extracted water was analyzed following USP <85> Bacterial Endotoxins Test and USP <161> Transfusion and infusion assemblies and similar medical devices protocols.

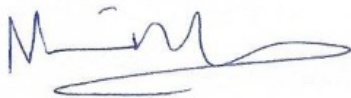
BACTERIAL ENDOTOXINS

Chromogenic kinetic method

Result	<0.339	EU/device
Detection limit	0.005	EU/mL
Method	USP <85> Bacterial Endotoxins Test USP <161> Transfusion and infusion assemblies and similar medical devices	
Devices tested	3	
Volum of the rinse	150	ml
Endotoxin allowed	20	EU/device

The **Soda Pasteur Pipette** sample with lot **5036** did fulfill mandatory LAL test criteria.

Nuno Costa-Borges, PhD



Scientific Director

Gloria Calderón, PhD



Quality Assurance