

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

OPERATION PROCEDURE: SOP-LAL-00/WI-LAL-03

INTERNAL NUMBER: LAL.020.1635.2023

DATE: 30/06/2023 - 30/06/2023

Product information provided by the customer (Embryotools cannot be held responsible for the veracity of this information)

DESCRIPTION OF TEST PRODUCT: Soda Pasteur Pipette

REF: PPS

LOT NUMBER: 5061

EXP. DATE: 2027-04

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	<0,250	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 **5061** did fulfill mandatory LAL test criteria.

These results are representative of the test samples submitted by the customer.

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Quality Assurance