

TITLE: Certificate of Analysis – Pyrogen Free Products

Date: 08 Dec 2025

This is to certify that the following goods have been sampled and tested for Endotoxin under the controlled conditions to conform to the relevant Thermo Fisher Scientific quality specifications.

Product has been sterilised by Gamma Irradiation, at a validated dose to ensure a Sterility Assurance Level of  $10^{-6}$ . Sterility is obtained through irradiation according to ISO 11137 (sterilization of health care products – requirements for validation and routine control – radiation sterilization).

Product Description:	30ml Uni Non-Pyrogenic	Lot:	M578970
Product Code:	128PYR	Expiry:	2030-11-20
Pyrotell T Lysate:	524-03-010-T	Standard Curve Specification:	Correlation Coef >0.980
Concentration:	4,500 EU/Vial or 900 EU/ml when reconstituted in 5ml LRW	Specification	<0.01EU/ml
CSE Lot (Control Standard Endotoxin)	186	Incubation Temperature (Mean)	36.8°C
LRW Lot (LAL Regent Water)	AJ03703070	Tested by:	A. Price

	Min (kGy)	Max (kGy)	Certificate of Irradiation	Date of Irradiation
Calculated Dose	20.7	26.7	47,489	05 Dec 25
Specification	15.0	35.0		

Correlation Coefficient of the Lot: - 0.999	Result Summary: Pass
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Signed on behalf of the Quality Department:



LIVIA HAVLICKOVA  
Batch Release-Document Controller