

TITLE: Certificate of Analysis – Pyrogen Free Products

Date: 30 May 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:	250ml Container Non - Pyrogenic	Lot:	M556630
Product Code:	190PYR	Expiry:	2030-03-05
Pyrotell T Lysate:	523-03-014-T	Standard Curve Specification:	Correlation Coef >0.980
Concentration:	7,500 EU/Vial or 1,500 EU/ml when reconstituted in 5ml LRW	Specification	<0.01EU/ml
CSE Lot (Control Standard Endotoxin)	181	Incubation Temperature (Mean)	36.9°C
LRW Lot (LAL Regent Water)	AH29961741	Tested by:	A. Price

	Min (kGy)	Max (kGy)	Certificate of Irradiation	Date of Irradiation
Calculated Dose	19.6	28.0	2163-12092A	25/26 May 25
Specification	15.0	35.0		

Correlation Coefficient of the Lot: - 0.988	Result Summary: Pass
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Signed on behalf of the Quality Department:



Position
 LIVIA HAVLICKOVA
 Batch Release-Document Controller