CERTIFICATE OF ANALYSIS

Reference Number:	PE3XX11
Lot Number:	XX-XXX.XX
Storage Temperature:	-40°C to -20°C
Expiration Date:	XX/XXXX
Product Origin:	EU

DESIGNATION

ELAREM™ Perform-FD PLUS (Research Grade) is a fibrinogen-depleted and heparin-free Human Platelet Lysate of EU origin. The xeno-free cell culture supplement is derived from human platelets collected from healthy donors at licensed blood centres following European guidelines. **ELAREM™ Perform-FD PLUS (Research Grade)** is obtained from multiple donor units pooled in large batch sizes to produce a consistent product.

INTENDED USE

ELAREM™ Perform-FD PLUS (Research Grade) is for Research Use Only (RUO). Not for any animal, human or therapeutic use. For safety precautions, please see appropriate Safety Data Sheet (SDS).

TEST	METHOD	SPECIFICATIONS	RESULTS
Appearance	Ph. Eur. 11.0, 2.9.20.	Yellow to orange liquid, free of visible large aggregates*	
Sterility	Ph. Eur. 11.0, 5.1.6.	No growth	
Mycoplasma	Ph. Eur. 11.0, 2.6.21.	Not detected	
Endotoxin	Ph. Eur. 11.0, 2.6.14.	< 5 EU/mL	
Osmolality	Ph. Eur. 11.0, 2.2.35.	250-350 mOsm/kg	
pH	Ph. Eur. 11.0, 2.2.3.	7.0-9.0	
Cell Growth Performance	Cell proliferation for hMSC	Promotes *in vitro* propagation and maintenance of adherent human cells	
Total protein	Ph. Eur. 11.0, 2.5.33. Bicinchoninic Acid Method (BCA)	> 2.1 g/dL	
Fibrinogen	Quantitative competitive ELISA - Human Fibrinogen	< 15 µg/mL	

* Insoluble particles or turbidity may appear after thawing the product.

ELAREM™ Perform-FD PLUS (Research Grade) is manufactured from platelet units obtained from healthy blood donors at licensed blood centres in the EU. Donors have been tested and found negative for HBsAg, Anti-HIV, Anti-HCV, HBV-NAT, HIV-NAT, HCV-NAT and Treponema pallidum (Syphilis).

Note: Despite all testing, proper safety precautions for potentially infectious agents must be taken. All human blood products should be handled in accordance with currently acceptable biosafety practices and guidelines for the prevention of blood borne viral infections.

Quality Department Date

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