neoFroxx
For a greener laboratory

neoFroxx GmbH

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Specification

Product	**Human Platelet Lysate fibrinogen-depleted & gamma-irradiated, GMP grade for cell biology**

Product number	2322 (revised)
Synonym(s)	Lysate of human thrombocytes; growth factor rich supplement for cell culture media
Storage	-20°C
Retest period (months)	36 (revised)

Human Platelet Lysate for cell biology, Fibrinogen-depleted & Gamma-irradiated, GMP grade is a gamma-irradiated cell culture supplement derived from human platelets collected from healthy donors at licensed blood centres following FDA guidelines. Multiple donor units are pooled in large batch sizes to produce a consistent product. It is manufactured, tested and released in compliance with the relevant GMP guidelines. The product is gamma-irradiated at a dose of 25~40 kGy.

This product is for in vitro and manufacturing use only. The product is not intended for direct therapeutic use. It is manufactured from platelet units obtained from healthy blood donors at FDA licensed blood centers. Donors have been tested using FDA-licensed tests and found negative for HBsAg, Hepatitis B core antibody (anti-HBc), HIV antibody (anti-HIV-1/2), Hepatitis C antibody (anti-HCV), HTLV-1/2 antibody (anti-HTLV-1/2), Trypanosoma cruzi antibody (anti-T. cruzi), HIV-1, HCV, HBV, WNV nucleic acid testing and Syphilis microhemagglutination test. Each donation is tested for ZIKV under either an FDA licensed test or an investigational ID-NAT test and found non-reactive.

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.

Parameter	**Specification**
Appearance	yellow to buff liquid
Sterility	no microbial growth
Mycoplasma	not detected
Endotoxin	≤ 10 EU/mL
Osmolality	passes test
pH	passes test
Performance test	promotes growth and expansion of human mesenchymal stem cells for more than 3 passages
Total protein	4.0 - 8.0 g/dL

Einhausen, 05.02.2024 (revised)