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	Title:	TECHNICAL DATASHEET		

Human Platelet Lysate

Treatment	0.2 µm sterile filtered, Pooled, Defibrinated
Product Code	HPL-001-100ML
Origins	EU
Pack Size	100mL
Shelf Life	5 Years from DOM
Storage Temperature	≤ -15°C
Shipping Temperature	≤ -15°C

QC Specifications

Physical and Chemical Analysis	Method	Specifications	Units
Identity	Internally Validated	Human	n/a
Appearance	Visual	Clear yellow-amber	n/a
pH at RT	Electronic pH Meter	6.8 - 7.8	n/a
Osmolality	Osmometer	250 - 330	mOsm/kg
Endotoxin	LAL Kinetic	< 10	EU/mL
Hemoglobin	Colorimetric	< 30	mg/dL

Sterility

Test	Method	Specifications	Units
Aerobic Bacteria	Internally Validated	Not detected	n/a
Anaerobic Bacteria	Internally Validated	Not detected	n/a
Fungi (Yeast & Mold)	Internally Validated	Not detected	n/a

Virology and Infectivity Analysis

Each individual blood donation has been tested for HIV-1/2 antibodies, HCV antibodies, and HBs antigen with CE-marked methods cleared in compliance with the European Directive 98/79/EC, Annex II, List A and found negative or non-reactive.

Ethical Remarks

The samples were gained, processed, and verified in a way that is ethically and legally compliant for the purposes of diagnostic research and development, production, and quality assurance. All products are from human sources resulting in variances of state, color, and turbidity that do not diminish their quality.

Instructions for Use

- Thaw Human Platelet Lysate in a 37°C water bath. Mix well.
- Avoid thaw-freeze cycles. Once aliquots are thawed, do not re-freeze
- Product has been aseptically filtered with 0.2 µm filters. Particulates will be observed after thawing. Particulate formation is normal will not affect performance even in the presence of large particulates. Filtration is not recommended.
- To reduce particulates from forming, minimize freeze/thaw cycles and extend storage at 4°C. Some particulate formation can be reversed with brief incubation at 37°C, if desired.
- Adding heparin to the media at a final concentration of 2 U/mL is highly recommended to avoid any risk of coagulation and gel formation. Failure to add heparin may result in coagulation of certain media.
- For optimal growth of human mesenchymal stem cells, add 5% (2-10%) vol/vol HPL-001 to the usual cell culture medium such as DMEM and MEM α modification. Optimal concentration must be determined for each cell type, cell line, and/or application.
Plate cells at approximately 1.5x10³ cells per cm².
- Do not allow primary MSC confluence to exceed 80%.

Intended Use and Disclaimer

Human platelet lysate is a growth factor-rich cell culture supplement derived from healthy donor human platelets from EU origin. Multiple donor units are pooled during manufacturing to minimize lot-to-lot variability. Addition of an anticoagulant is required to inhibit coagulation. They are for research or manufacturing purposes only and are not for direct therapeutic or diagnostic use in humans or animals. Identifying genetic analyses as well as genetic analyses for the diagnosis of possible diseases or potential risks of the respective donors are not admissible with this material. Biospecimens should be treated as potentially infectious. Therefore, standard precautions for safe handling and disposal are advised.

ALL BLOOD PRODUCTS SHOULD BE HANDLED AND TREATED AS POTENTIALLY INFECTIOUS.

Product Use: NOT FOR USE IN HUMANS OR CLINICAL DIAGNOSIS. THESE PRODUCTS ARE INTENDED FOR RESEARCH OR DIAGNOSTIC MANUFACTURING USE ONLY.