

## Human Platelet Lysate (hPL)

### Product Description

Human Platelet Lysate (hPL) is a cell culture growth supplement obtained from human platelets. HPL contains abundant growth factors and cytokines necessary for cell growth and proliferation. Human Platelet lysate can be used as a replacement for traditional foetal bovine supplemented cell culture medium. Replacing foetal bovine serum (FBS) with hPL allows for expansion and potential clinical grade production of functional mesenchymal stromal cells by removing the risk of xenogeneic immune reactions and transmission of bovine prion and viral pathogens.

European guidelines require that bovine material should be removed from culturing media wherever possible for any therapeutic product containing cultured cells. HPL is a suitable alternative for use in R&D and production/ manufacturing processes.

Other advantages for the use of hPL in research and cell therapy applications include:

- Pooled from multiple donors. The consistent supply of donor platelets helps to stabilize availability and pricing.
- A standardized, qualified product which is manufactured to reduce batch-to-batch variation.
- Human-derived (animal-protein free) product which has been subject to extensive serology testing ensures safety for each batch.
- Improves the proliferation of Mesenchymal Stromal Cells (MSCs) compared to FBS without loss of phenotype.
- Can be used for the expansion of other cell types, including fibroblasts and adipocytes.
- Enhances genetic stability in stem cell cultures.

### Recommended for

- Human Mesenchymal Stromal Cells from Bone Marrow (hMSC-BM)
- Human Mesenchymal Stromal Cells from Umbilical Cord (hMSC-UC)
- Human Mesenchymal Stromal Cells from Adipose Tissue (hMSC-AT)
- Human Dermal Fibroblasts (HDF)

### Formats

**Human Platelet Lysate Solution Standard** – requires the addition of heparin prior to use. Choose from a standard animal derived heparin (porcine), or a xeno-free heparin (fully synthetic and preservative free).

**Human Platelet Lysate Solution-FD** – A fibrin-depleted hPL that does not require the addition of heparin prior to use. However, it may contain residues of heparin. For human ex-vivo tissue and cell culture processing applications. This is available as both Research and GMP Grade

**Human Platelet Lysate Solution-XF** – A completely xeno-free fibrin-depleted hPL without heparin. Does NOT require the addition of heparin prior to use unlike the standard and FD versions. For human ex-vivo tissue and cell culture processing applications. This is available as both Research and GMP Grade

**Platelet Matrix** – is a two-phase cell culture system that provides a 3D-matrix for cell growth of adherent cells, but which enables non-enzymatic passaging by simply pipetting. Used in conjunction with PL Solution.

**FBS Replacement** – this is a formulation of human platelet lysate developed as a replacement for foetal bovine serum. This product contains abundant growth factors and cytokines derived from human platelets which stimulate cellular proliferation and maintain phenotype and differentiation potential of stem cells.

**FBS Replacement** supports the *in vitro* propagation and maintenance of various human cell types, including Mesenchymal Stromal Cells, Dermal Fibroblasts, Epidermal Keratinocytes and Endothelial Colony Forming Cells.

## Donor Qualification and Testing

HPL is derived from human donor platelets collected from healthy consented volunteer donors at certified German Blood banks (21CFR640). All individual donors and complete batches are fully tested for pathogens according to 21CFR610.

## Specifications

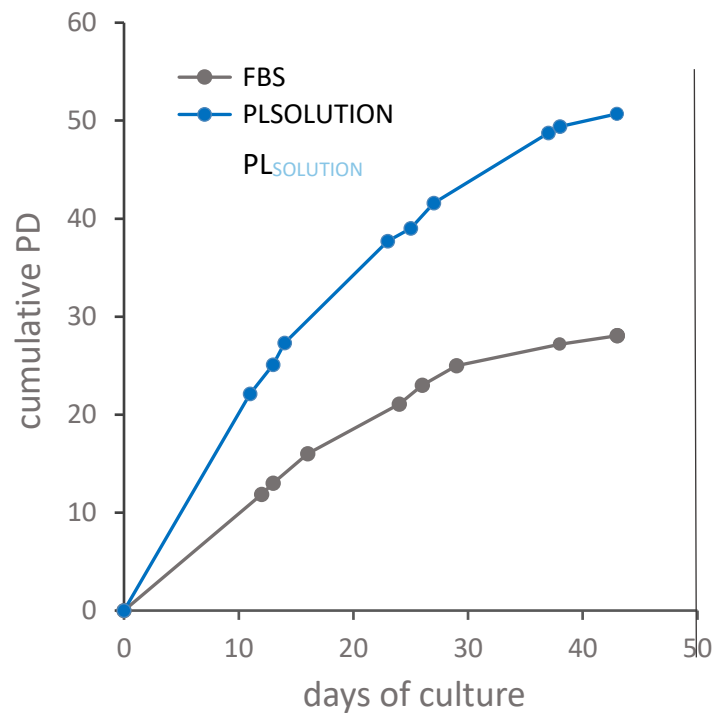
**Human Platelet Lysate Solution** is a cell culture supplement derived from human Platelet Rich Plasma (PRP) which is subjected to a freeze-thaw process to induce growth factors release.

<b>Country of Origin</b>	Germany
<b>Sterility</b>	Each batch is tested for the absence of bacteria, fungi, yeast and mycoplasma.
<b>Viral Testing</b>	Each batch is tested and found non-reactive for HBsAg, HIV I/II antibody, CMV, HCV- and HBC-Antibody, HIV-, HCV-, HBV-, HAV-, PVB19-NAT, Treponema pallidum and Syphilis.
<b>Endotoxin</b>	All batches are tested to determine the levels of endotoxins using the Limulus ameobocyte lysate test (LAL) - <10 EU/mL.
<b>Growth promotion</b>	Biological performance of final batches of hPL are assessed by cell culture on MSC, Fibroblasts and Primary cells.
<b>Mycoplasma</b>	Tested for <i>M. fermentans</i> , <i>M. arginini</i> , <i>M. orale</i> , <i>M. hyorhinis</i> , <i>M. salivarium</i> , <i>M. hominis</i> , <i>M. pneumoniae</i> , <i>Acholeplasma laidlawii</i> , <i>M. synoviae</i> and Ureaplasma species.
<b>Filtration</b>	Batches of hPL are sequentially filtered to 0.2 and finally 0.1 micron to ensure sterility before being dispensed, aseptically into sterile bottles (or Cryo-bags for GMP-Grade hPL).

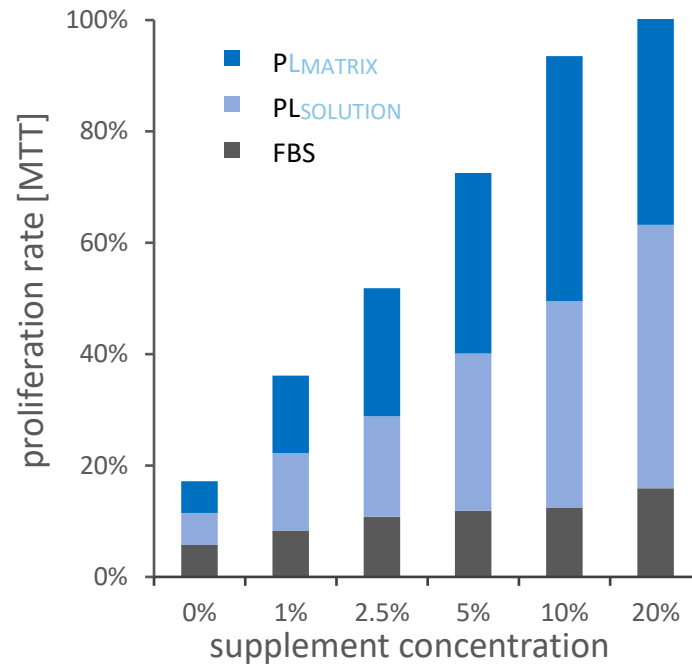
Complete results are reported on the Certificate of Analysis supplied with each batch.

## Performance

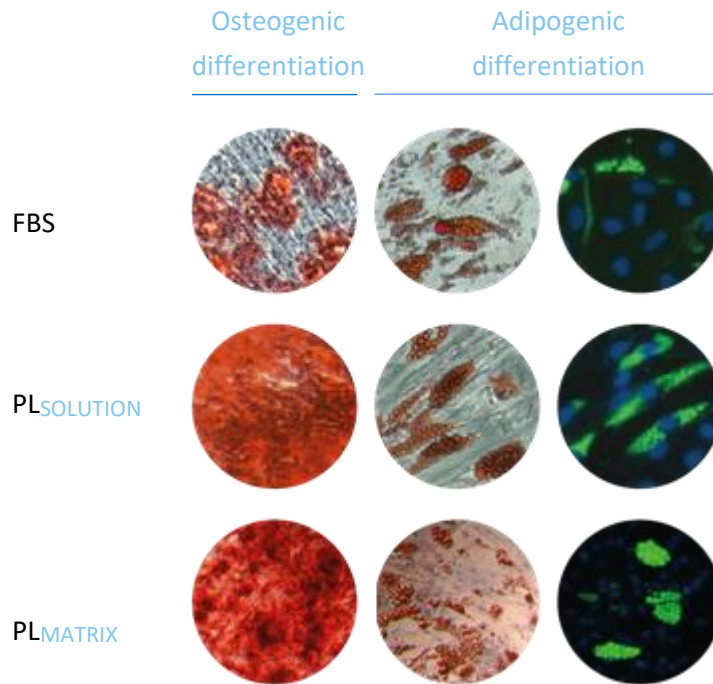
**Population doubling:** Cumulative population doubling of bone marrow-derived MSC was higher in [Human Platelet Lysate Solution](#) compared to FBS.



**Proliferation rate:** Proliferation of human bone marrow-derived MSC increased in a concentration-dependent manner with **Platelet Matrix**, **Human Platelet Lysate Solution** and FBS, respectively.



**Differentiation potential:** Osteogenic and adipogenic differentiation potential of human bone marrow-derived MSC in FBS, Human Platelet Lysate Solution and Platelet Matrix.



## Product Information

Human Platelet Lysate is available in three formats:

- [Human Platelet Lysate](#) standard - requires supplementation with heparin prior to use
- [Human Platelet Lysate FD](#) - no heparin supplementation is required.
- [Human Platelet Lysate XF](#) - a completely xeno-free fibrin-depleted hPL (no heparin supplementation required)
- All three formats are available as Research Grade and GMP Grade material. Gamma irradiated material is also available (GMP grade only).

Product Code	Product Description	Pack Size
<b>Human Platelet Lysate Solution</b> (these products require the addition of heparin)		
PLS-001K	<a href="#">Human Platelet Lysate</a> - Research Grade	25mL
PLS-001B	<a href="#">Human Platelet Lysate</a> - Research Grade	100mL
PLS-001A	<a href="#">Human Platelet Lysate</a> - Research Grade	500mL
PLS-002B-BAG-GMP	<a href="#">Human Platelet Lysate</a> - GMP Grade (cryobag)	100mL
PLS-002B-GMP	<a href="#">Human Platelet Lysate</a> - GMP Grade	100mL
PLS-002A-GMP	<a href="#">Human Platelet Lysate</a> - GMP Grade	500mL
PLS-002C-GMP-GI	<a href="#">Human Platelet Lysate</a> - GMP Grade, gamma irradiated	50mL
PLS-002B-GMP-GI	<a href="#">Human Platelet Lysate</a> - GMP Grade, gamma irradiated	100mL
PLS-002A-GMP-GI	<a href="#">Human Platelet Lysate</a> - GMP Grade, gamma irradiated	500mL
PLA-001M	<a href="#">Heparin</a> - Porcine Heparin (5.000 U/mL)	0.5 mL
PLA-XF-001M	<a href="#">Platelet Supplement-XF</a> – Xeno-free Heparin (12.5mg/mL)	0.5 mL
<b>Human Platelet Lysate FD</b> (no heparin required)		
HPL-FD-003E	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - Research Grade	10mL
HPL-FD-003C	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - Research Grade	50mL
HPL-FD-003B	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - Research Grade	100mL
HPL-FD-003A	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - Research Grade	500mL
HPL-FD-004E	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - GMP Grade	10mL
HPL-FD-004C	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - GMP Grade	50mL
HPL-FD-004B	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - GMP Grade	100mL
HPL-FD-004A	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - GMP Grade	500mL
HPL-FD-004C-GI	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - GMP Grade, gamma irradiated	50mL
HPL-FD-004B-GI	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - GMP Grade, gamma irradiated	100mL
HPL-FD-004A-GI	<a href="#">Human Platelet Lysate FD</a> - Fibrinogen depleted - GMP Grade, gamma irradiated	500mL

<b>Human Platelet Lysate XF</b> (no heparin required)		
HPL-XF-001E	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - Research Grade	10mL
HPL-XF-001C	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - Research Grade	50mL
HPL-XF-001B	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - Research Grade	100mL
HPL-XF-001A	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - Research Grade	500mL
HPL-XF-002E	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - GMP Grade	10mL
HPL-XF-002C	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - GMP Grade	50mL
HPL-XF-002B	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - GMP Grade	100mL
HPL-XF-002A	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - GMP Grade	500mL
HPL-XF-002C-GI	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - GMP Grade, Gamma Irradiated	50mL
HPL-XF-002B-GI	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - GMP Grade, Gamma Irradiated	100mL
HPL-XF-002A-GI	Human Platelet Lysate XF - 'xeno-free', fibrinogen-depleted, animal free - GMP Grade, Gamma Irradiated	500mL
<b>Platelet Matrix</b> (Heparin Accelerator needed to induce gelation)		
PLM-001G	Platelet Matrix - 3D Cell Culture System - Research Grade	1 mL
PLM-001F	Platelet Matrix - 3D Cell Culture System - Research Grade	5 mL
PLM-002K	Heparin Accelerator (10 mg/mL)	0.25 mL
<b>FBS Replacement</b>		
HPL-001E	Human Platelet Lysate, FBS Replacement - Research Grade	10 mL
HPL-001B	Human Platelet Lysate, FBS Replacement - Research Grade	100 mL
HPL-001A	Human Platelet Lysate, FBS Replacement - Research Grade	500 mL
<b>Human Platelet Units</b>		
HPU-001N	Human Platelet Units - expired, frozen	200 mL
HPU-001L	Human Platelet Units - expired, frozen	1000 mL

### What is the difference between Research Grade and GMP-Clinical Grade?

**Research Grade** material is manufactured to meet the needs of basic research and development. This material supports the *in vitro* propagation and maintenance of various human cell types. In addition, it provides a cost effective alternative to using serum-free media. Material is supplied in validated PETG NALEGENE flasks (25 mL and 100 mL).

**GMP-Clinical Grade** material is manufactured under GMP-controlled conditions using high quality raw materials, for use in GMP compliant cell culture SOPs. Processing of GMP-Clinical grade hPL is performed within closed system using sterile conditions. This material is provided in cryo-bags (100 mL).

## Quality

Each batch of hPL is produced from multiple donor units of > 300, producing a batch size of approx. 72-75 L. Donor units are pooled into large batch sizes to produce a consistent product with minimal batch-to-batch variation. HPL is bFGF and EGF qualified, and also Human MSC and dermal fibroblast qualified.

## Batch Sampling

Samples of hPL are available for testing prior to selection of a suitable batch. Typical sample size is 25 mL and reservations are held for a period of four weeks, pending evaluation.

## Concentration

Human Platelet Lysate can be used at a variety of concentrations, from 10% in basal media to as little as 2.5%. The table below indicates the concentrations of hPL used for a variety of different cell types and applications.

## Shelf life

Shelf life is 9-12 months from the date of manufacture.

## Storage & Handling

Recommended storage is -20°C or below. Long term storage -80°C.

It is recommended to avoid freeze-thaw cycles as this can lead to an increase in the formation of insoluble particles. Ideally, material should be thawed under controlled conditions and re-aliquoted into smaller volumes before re-freezing.

To use: pre-warm an aliquot of the complete MSC culture medium for 1 hour in a 37°C waterbath and keep the remaining medium refrigerated at 4 to 8 °C.

Pooling of hPL from multiple donors is routinely performed to provide a consistent product. Upon thawing the product may be physically cloudy or have floating debris. Particulate formation does not affect cell culture performance. This is normal and happens commonly from aggregation due to alloimmune reaction, even when donors are the same blood type. If clotting or insoluble particles appears in the final medium, it is recommended to filter the complete MSC culture medium after diluting the basal medium, to remove insoluble particulates.

## Shipping

Product ships frozen on dry ice.

## Literature

1. Astori, G., *et al.* (2016) Platelet lysate as a substitute for animal serum for the ex-vivo expansion of mesenchymal stem/stromal cells: present and future. *Stem Cell Res Ther.*, 7:93.



2. Azouna, N. B., *et al.* (2012) Phenotypical and functional characteristics of mesenchymal stem cells from bone marrow: comparison of culture using different media supplemented with human platelet lysate or fetal bovine serum. *Stem Cell Res Ther.*, 3(1):6.
3. Barsotti, M. C., *et al.* (2013) Effect of platelet lysate on human cells involved in different phases of wound healing. *PLOS*, 8(12): e84753.
4. Bieback, K., *et al.* (2009) Human alternatives to fetal bovine serum for the expansion of mesenchymal stromal cells from bone marrow. *Stem Cell*, 27(9):2331-2341.
5. Burnouf, T., *et al.* (2012) Human blood-derived fibrin releasates: Composition and use for the culture. *Biologicals*, 40: 21-30.
6. Burnouf, T., *et al.* (2015) Human platelet lysate: Replacing fetal bovine serum as a gold standard for human cell propagation? *Biomaterials*, 76: 371-387.
7. Capelli, C., *et al.* (2007) Human Platelet Lysate allows expansion and clinical grade production of mesenchymal stromal cells from small samples of bone marrow aspirates or marrow filter washouts. *Bone Marrow Transplant*, 40(8):785-791.
8. Castegnaro, S., *et al.* (2011) Effect of platelet lysate on the functional and molecular characteristics of mesenchymal stem cells isolated from adipose tissue. *Curr Stem Cell Res Ther.*, 6(2):105-114.
9. Cholewa, D., *et al.* (2011) Expansion of adipose mesenchymal stromal cells is affected by human platelet lysate and plating density. *Cell Transplant*, 20(9):1409-1422.
10. Doucet, C., *et al.* (2005) Platelet lysates promote mesenchymal stem cell expansion: a safety substitute for animal serum in cell-based therapy applications. *J Cell Physiol.*, 205(2):228-236.
11. Fazzina, R., *et al.* (2015) Culture of human cell lines by a pathogen-inactivated human platelet lysate. *Cytotechnology*, DOI 10.1007/s10616-015-9878-5
12. Fernandez-Rebollo, E., *et al.* (2017) Human Platelet Lysate versus Fetal Calf Serum: These supplements do not select for different Mesenchymal Stromal Cells. *Scientific Reports*, DOI 10.1038/s41598-017-05207-1.
13. Fekete, N., *et al.* (2012) Platelet lysate from whole blood-derived pooled platelet concentrates and apheresis-derived platelet concentrates for the isolation and expansion of human bone marrow mesenchymal stromal cells: production process, content and identification of active components. *Cytotherapy*, 2012; 14(5):540-554.
14. Govindasamy, V., *et al.* (2011) Human platelet lysate permits scale-up of dental pulp stromal cells for clinical applications. *Cytotherapy*, 13(10):1221-1233.
15. Hemeda, H., *et al.* (2013) Heparin concentration is critical for cell culture with human platelet lysate. *Cytotherapy*, 15(9):1174-1181.
16. Hemeda, H., *et al.* (2014) Evaluation of human platelet lysate versus fetal bovine serum for culture of mesenchymal stromal cells. *Cytotherapy*, 16(2):170-180.
17. Horn, P., *et al.* (2010) Impact of individual platelet lysates on isolation and growth of human mesenchymal stromal cells. *Cytotherapy*, 12(7):888-898.
18. Naaijken, B.A., *et al.* (2012) Human platelet lysate as a fetal bovine serum substitute improves human adipose-derived stromal cell culture for future cardiac repair applications. *Cell Tissue Res.*, 348(1):119-130.
19. Rauch, C., *et al.* (2011) Alternatives to the use of fetal bovine serum: Human platelet lysates as a serum substitute in cell culture media. *ALTEX*, 28(4):305-316.
20. Ruggiu, A., *et al.* (2013) The effect of Platelet Lysate on osteoblast proliferation associated with a transient increase of the inflammatory response in bone regeneration. *Biomaterials*, 34: 9318-9330.
21. Schallmoser, K., *et al.* (2007) Human platelet lysate can replace fetal bovine serum for clinical-scale expansion of functional mesenchymal stromal cells. *Transfusion*, 47(8):1436-1446.

22. Suri, K., *et al.* (2014) Platelet Lysate as replacement for fetal bovine serum in limbal stem cell cultures: Preliminary results. *Investigative Ophthalmology & Visual Science*, 55: 511.
23. Trojahn Kølle, S.F., *et al.* (2013) Pooled human platelet lysate versus fetal bovine serum-investigating the proliferation rate, chromosome stability and angiogenic potential of human adipose tissue-derived stem cells intended for clinical use. *Cytotherapy*, 15(9):1086-1097.
24. Walenda, G., *et al.* (2012) Human platelet lysate gel provides a novel three dimensional-matrix for enhanced culture expansion of mesenchymal stromal cells. *Tissue Eng Part C Methods*, 18(12):924-934.

## Precaution

All Human derived products have been thoroughly tested to strict guidelines. However, while all of the human donors that go into producing each batch of human serum have been tested and have been found negative for several virus antibodies and antigens, there is no known test method can offer complete assurance that human derived blood products are not capable of transmitting an infectious disease. It is therefore important that human platelet lysate be considered potentially infectious and handled accordingly.

## Disclaimer

For research use only. Not for therapeutic or diagnostic use.

## Support

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