

## 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 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 FD** – A fibrinogen-depleted hPL that does NOT require the addition of heparin to the cell culture mix. However, it may contain residues of heparin. For human *ex-vivo* tissue and cell culture processing applications. These products are also available gamma irradiated.

**Human Platelet Lysate XF** – A completely xeno-free, fibrinogen-depleted hPL. Does NOT require the addition of heparin to the cell culture mix. For human *ex-vivo* tissue and cell culture processing applications. These products are also available gamma irradiated.

**Human Platelet Lysate-Customised** – A made-to-order cell culture supplement. Requires the addition of heparin prior to use. Designed for small-scale process development.

**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 hPL Solution.

**Mesenchymal Stem Cell Kit** – is a kit comprising of a basal medium and a growth supplement specific for the cultivation of Mesenchymal Stem Cells (MSCs).

**Human-derived Mesenchymal Stem Cells** - highly characterised and functionally validated human Mesenchymal Stem Cells (MSCs) isolated out of adipose tissue or bone marrow from healthy donors.

## 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

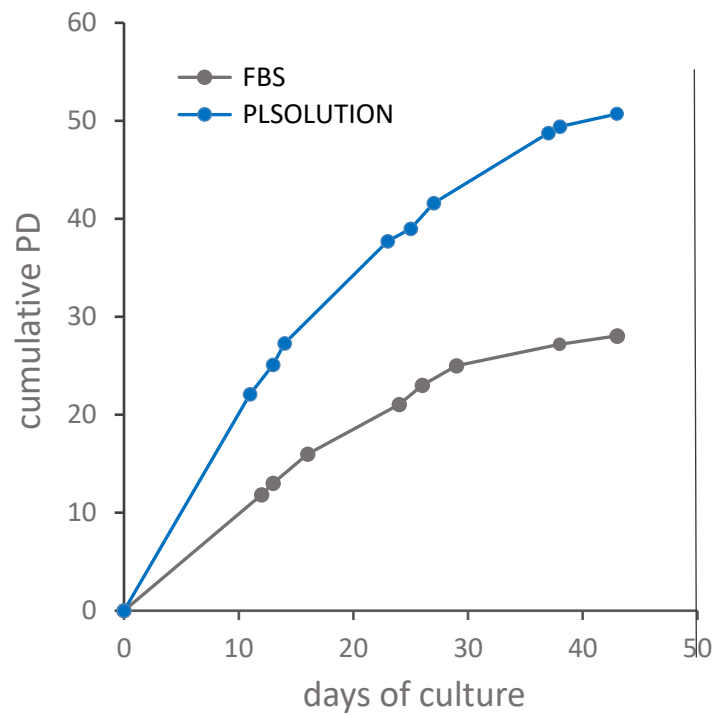
**Human Platelet Lysate Solution** is a cell culture supplement derived from human Platelet Rich Plasma (PRP) which is subjected to a freeze-thaw process to induce growth factors release.

<b>Country of Origin</b>	Germany
<b>Sterility</b>	Each batch is tested for the absence of bacteria, fungi, yeast and mycoplasma.
<b>Pathogen 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, <i>Treponema pallidum</i> and <i>Syphilis</i> .
<b>Endotoxin</b>	All batches are tested to determine the levels of endotoxins using the Limulus amoebocyte 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. hyorhinitis</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).

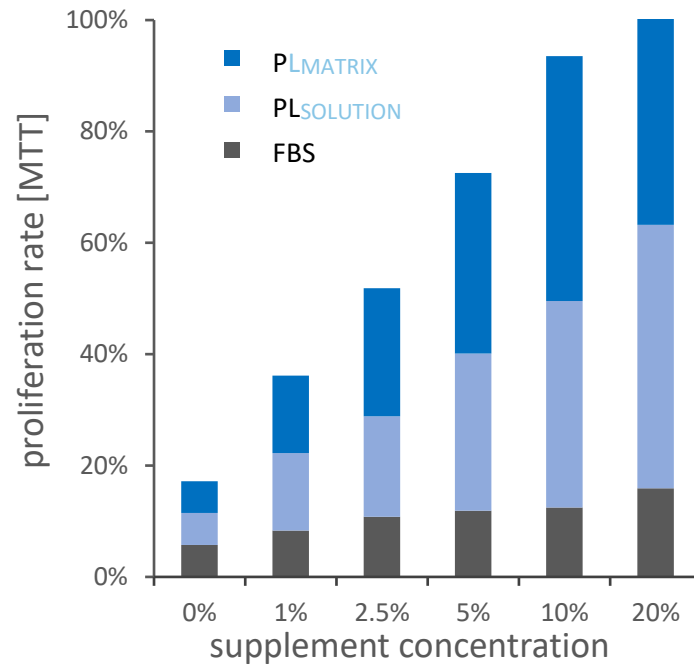
Complete results are reported on the Certificate of Analysis supplied with each batch.

## Performance

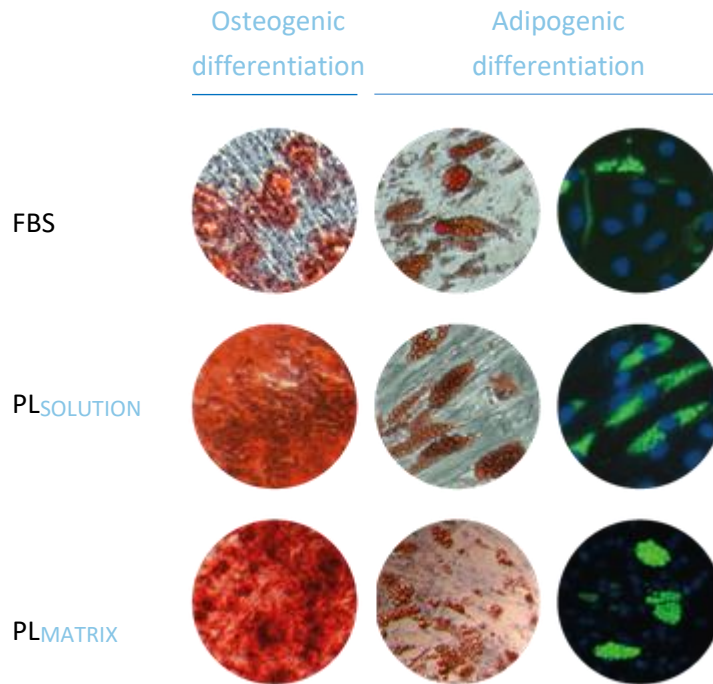
**Population doubling:** Cumulative population doubling of bone marrow-derived MSC was higher in [Human Platelet Lysate Solution](#) compared to FBS.



**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 four 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).
- [Human Platelet Lysate-Customised](#) – a customisable option for small-scale process development (requires the addition of heparin).

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-001A	<a href="#">Human Platelet Lysate</a> - Research Grade	500mL
PLS-001B	<a href="#">Human Platelet Lysate</a> - Research Grade	100mL
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
HSUP-001M	<a href="#">HPL supplement</a> - Heparin (5,000 U/mL)	0.5mL
HSUP-XF-001M	<a href="#">HPL supplement</a> - Heparin (12.5 mg/mL) - xeno-free	0.5mL
<b>Human Platelet Lysate FD</b> (Fibrinogen-depleted, no heparin required)		
HPL-FD-003C	<a href="#">Human Platelet Lysate -FD</a> Fibrinogen depleted - Research	50mL
HPL-FD-004C	<a href="#">Human Platelet Lysate -FD</a> Fibrinogen depleted - GMP Grade	50mL
HPL-FD-004C-GI	<a href="#">Human Platelet Lysate -FD</a> Fibrinogen depleted - GMP Clinical Grade	50mL
HPL-FD-003B	<a href="#">Human Platelet Lysate -FD</a> Fibrinogen depleted - Research Grade	100mL
HPL-FD-004B	<a href="#">Human Platelet Lysate -FD</a> Fibrinogen depleted - GMP Grade	100mL
HPL-FD-004B-GI	<a href="#">Human Platelet Lysate -FD</a> Fibrinogen depleted - GMP Clinical Grade	100mL
HPL-FD-003A	<a href="#">Human Platelet Lysate -FD</a> Fibrinogen depleted - Research Grade	500mL
HPL-FD-004A	<a href="#">Human Platelet Lysate -FD</a> Fibrinogen depleted - GMP Grade	500mL
HPL-FD-004A-GI	<a href="#">Human Platelet Lysate -FD</a> Fibrinogen depleted - GMP Clinical Grade	500mL
<b>Human Platelet Lysate XF</b> (Xeno-free, fibrinogen-depleted, animal free, no heparin required)		
HPL-XF-001C	<a href="#">Human Platelet Lysate XF</a> 'xeno-free' - Research Grade	50mL
HPL-XF-002C	<a href="#">Human Platelet Lysate XF</a> 'xeno-free' - GMP Grade	50mL
HPL-XF-002C-GI	<a href="#">Human Platelet Lysate XF</a> 'xeno-free' - GMP Clinical Grade	50mL
HPL-XF-001B	<a href="#">Human Platelet Lysate XF</a> 'xeno-free' - Research Grade	100mL
HPL-XF-002B	<a href="#">Human Platelet Lysate XF</a> 'xeno-free' - GMP Grade	100mL
HPL-XF-002B-GI	<a href="#">Human Platelet Lysate XF</a> 'xeno-free' - GMP Clinical Grade	100mL

HPL-XF-001A	Human Platelet Lysate XF 'xeno-free' - Research Grade	500mL
HPL-XF-002A	Human Platelet Lysate XF 'xeno-free' - GMP Grade	500mL
HPL-XF-002A-GI	Human Platelet Lysate XF 'xeno-free' - GMP Clinical Grade	500mL
<b>Human Platelet Lysate-Customised</b> (customisable, requires the addition of heparin)		
HPL-CUS-100B	Human Platelet Lysate-Customised	100mL
HPL-CUS-100A	Human Platelet Lysate-Customised	500mL
<b>Platelet Matrix</b> (Heparin Accelerator needed to induce gelation)		
PLM-001G	Platelet Matrix Research Grade - 3D Cell Culture System	1mL
PLM-001F	Platelet Matrix Research Grade - 3D Cell Culture System	5mL
PLM-002K	Heparin Accelerator [10 mg/mL] for use with Platelet Matrix	0.25mL
PLM-005K	Heparin Accelerator [10 mg/mL] for use with Platelet Matrix	0.05mL
<b>Mesenchymal Stem Cells (MSCs)</b>		
MSC-001A	Mesenchymal Stem Cell Medium kit, Xeno-free	500mL
MSC-002G	MSCs - Human Adipose Tissue-derived Mesenchymal Stem Cells	1mL
MSC-003G	MSCs - Human Bone Marrow-derived Mesenchymal Stem Cells	1mL
<b>Human Platelet Units</b>		
HPU-001N	Human Platelet Units, expired, frozen	200mL

### What is the difference between Research Grade, GMP 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 Nalgene bottles (25 mL, 100 mL and 500 mL).

**GMP Grade** material is manufactured under GMP-controlled conditions for use in GMP compliant cell culture SOPs. This material is provided in cryo-bags (100 mL) or in validated PETG Nalgene bottles (100 mL and 500 mL).

**GMP Clinical Grade** material is manufactured and gamma irradiated (at 25~40kGy) under GMP conditions to comply with the high safety guidelines for clinical applications. Due to pathogen-reduction, GMP Clinical Grade hPL provides a high safety level for expansion of different human cell types (particularly adult stem cells, e.g. MSCs) for clinical and therapeutic applications.

### 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

hPL can be used at a variety of concentrations, from 10% in basal media to as little as 2.5%.

## 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.

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.

## How do I use hPL?

1. Thaw [Human Platelet Lysate Solution](#) overnight at 4°C or for 1 hour in a 37°C water bath.
2. Prepare complete MSC culture medium by adding [Human Platelet Lysate Solution](#) to basal medium (i.e. Dulbecco's Modified Eagles Medium-Low Glucose; DMEM-LG) with 2 mM L-glutamine and 100 U/mL Penicillin/streptomycin as final concentration.
3. hPL shows optimal growth of MSC at 5% (v/v). However, for higher cell proliferation rates, it is recommended to use 10% (v/v) hPL.
4. We recommend seeding MSCs at approximately  $3 \times 10^3 \sim 6 \times 10^3$  per  $\text{cm}^2$ .
5. For [Human Platelet Lysate Standard](#) ONLY, heparin should be added at a final concentration of 2 U/mL [Heparin](#) (cat.no. HSUP-001M) or 0.024 mg/mL [Xeno-Free Heparin](#) (cat. no. HSUP-XF-001M) to avoid coagulation of the complete MSC culture medium.

NOTE: Human Platelet Lysate FD and Human Platelet Lysate XF DO NOT require the addition of heparin as they are fibrinogen-depleted products.

6. Complete MSC culture medium can be stored at 4°C and is stable for approximately four weeks.



## Shipping

Product ships frozen on dry ice.

## Literature

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## 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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