

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)

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.

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Specifications

Human Platelet Lysate 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.

Country of Origin	US/EU
Sterility	Each batch is tested for the absence of bacteria, fungi, yeast and mycoplasma.
Pathogen Testing	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> .
Endotoxin	All batches are tested to determine the levels of endotoxins using the Limulus amoebocyte lysate test (LAL) - <10 EU/mL.
Growth promotion	Biological performance of final batches of hPL are assessed by cell culture on MSC, Fibroblasts and primary cells.
Mycoplasma	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 <i>Ureaplasma</i> species.
Filtration	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.

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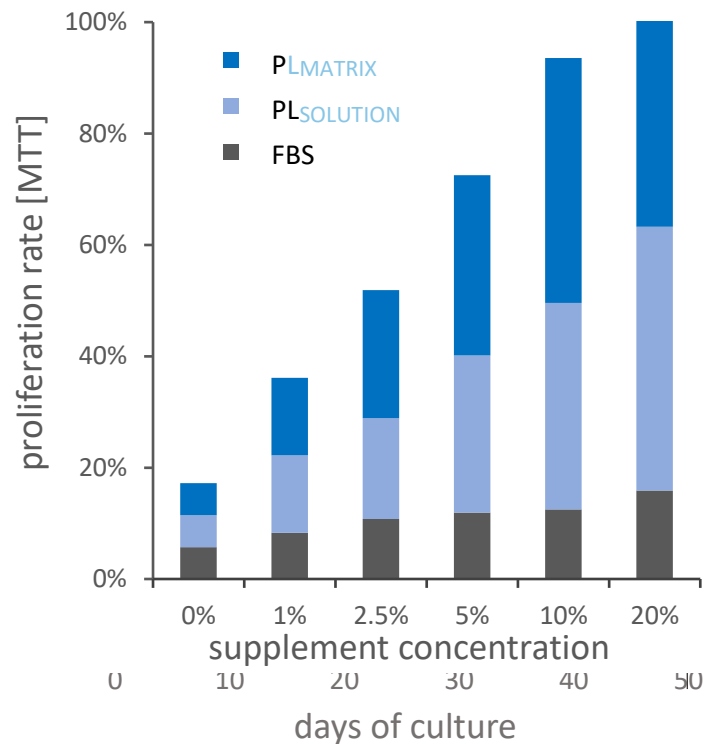
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Proliferation rate: Proliferation of human bone marrow-derived MSC increased in a concentration-dependent manner with [Platelet Matrix](#), [Human Platelet Lysate Solution](#) and FBS, respectively.



Differentiation potential: Osteogenic and adipogenic differentiation potential of human bone marrow-derived MSC in FBS, [Human Platelet Lysate Solution](#) and [Platelet Matrix](#).

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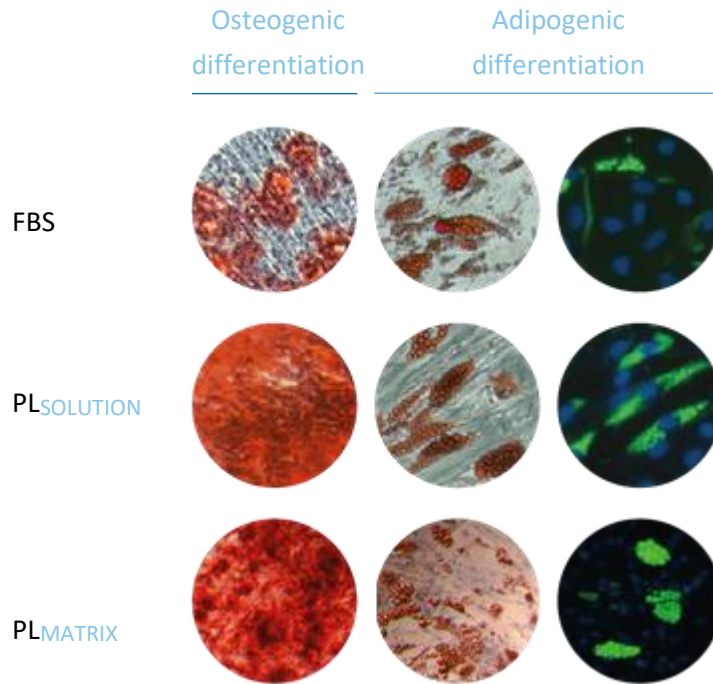
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Product Information

Human Platelet Lysate is available in the following formats:

Product Code	Product Description	Pack Size
HPL-500A-PR	Human Platelet Lysate (hPL) Clinical Grade GMP-ready pathogen reduced	500 mL
HPL-500B-PR	Human Platelet Lysate (hPL) Clinical Grade GMP-ready pathogen reduced	100 mL
HPL-500A-SP	Human Platelet Lysate (hPL) Clinical Grade	500 mL
HPL-500B-SP	Human Platelet Lysate (hPL) Clinical Grade	100 mL
HPL-500B-NH	Human Platelet Lysate (hPL) Research Grade	100 mL
HPL-500A-NH	Human Platelet Lysate (hPL) Research Grade	500 mL

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

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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.

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 cm^2 .
5. Complete MSC culture medium can be stored at 4°C and is stable for approximately four weeks.

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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.
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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.
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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.

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

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Life Science Group Ltd is an ISO 9001:2015 Certified company

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