

Doc. No.	Rev	Effective Date
PI26	4	29 Apr 2025

Human Platelet Lysate (hPL)

Product Description

Human Platelet Lysate (hPL) is a solution obtained by lysing human platelets. It contains a rich mix of growth factors, cytokines and other bioactive molecules that stimulate cell growth, regeneration and tissue repair. This makes it therefore ideally suited as a xeno-free supplement for (stem) cell culture in cell therapy production, among others. The development of hPL Gold and Platinum allows our provider to make the best use of all blood donations, as well as making an additional contribution to improved patient care.

hPL is made from exclusively human material, thus no animal products are involved. This not only increases compatibility with human cell culture but eliminates the risk of zoonotic infections as with FBS. When ultimately used for clinical purposes, there is no risk of patient immunization against animal proteins and is an additional argument to the regulator for approving your cultured cells.

Choosing hPL over FBS is also recommended for research groups. Not only is hPL often more efficient than FBS, it is, above all, an important choice for the long term of your project. When translating to a clinical setting by you or third parties, the use of FBS during research is a distinct disadvantage as it necessitates a switchover from FBS to hPL. As a result, your costly research must be re-lined with hPL. Using hPL Gold or Platinum from the starting line anticipates problems later in your path.

The preparation of hPL from donor to final product lies entirely with our preferred partnering blood establishment, thus we have excellent control over correct storage and handling of all source, intermediate and final products. During our development, production in a closed system was crucial, so the hPL never comes into contact with ambient air, whereas FBS or hPL from competitors often ends up in open systems both during collection at the slaughterhouse and during production.

Since the source product of hPL is standardized to meet strict requirements for transfusion, the batch-to-batch variation of hPL is a lot lower than for FBS. In addition, donor material from multiple donors is pooled, further reducing batch-to-batch variation.

Our partnering blood establishment has developed an innovative method to produce lysates from human blood platelets. The technique ensures that expired platelets are not lost and animal suffering is avoided.

Each year, thousands of platelet concentrates are discarded. As these can only be stored for five days, up to 10 per cent are destroyed. Our partnering blood establishment has now developed a biotech product that can make use of these "expired" platelets. Thanks to the new technique, the platelets can be used to develop growth serum, an important starting product for the development of vaccines or in cell and genetic engineering.

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Life Science Production

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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.
- Batch sizes, customized to client's needs
- 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 continuous cell lines like HEK293, CHO and HeLa cells. .
- 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)
- Continuous cell lines: HEK293, CHO and HeLa

Donor Qualification and Testing

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

Specifications

Human Platelet Lysate is a cell culture supplement derived from human Platelet Rich Plasma (PRP) is subjected to a proprietary process to induce growth factors release.

Country of Origin	EU
Sterility	Each batch is tested for the absence of bacteria and fungi.
Pathogen Testing	Each batch is tested and found non-reactive for anti-HIV-1/2, anti-HCV, HBsAg, syphilis, HIV NAT, HBV NAT and HCV NAT.

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Endotoxin	All batches are tested to determine the levels of endotoxins using the Limulus amoebocyte lysate test (LAL) - <0.500 EU/mL.
Growth promotion	Biological performance of final batches of hPL are assessed by cell culture of MSC.
Mycoplasma	Mycoplasma is tested by PCR technique.

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

Performance

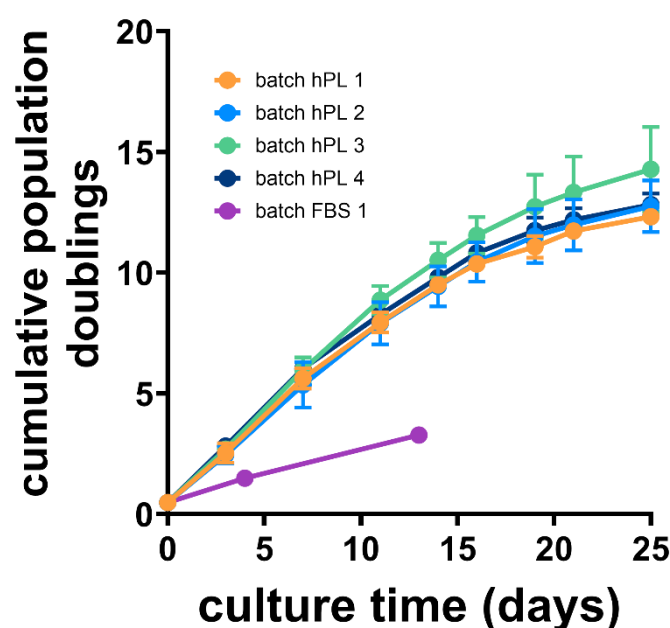


Figure Adipose derived mesenchymal stem cells were cultured separately in four different batches of Gold hPL supplemented at 10% (vol/vol) in DMEM-F12 basal medium. Cells were counted during expansion and the number of population doublings was recorded. As a control condition one batch of commercially available FBS was used at 10% as well.

Product Information

Human Platelet Lysate is available in the following formats:

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Product Code	Product Description	Size
HPL-600B-150	Human Platelet Lysate (hPL) GOLD Research Grade (150 donors)	100 mL
HPL-600B-25	Human Platelet Lysate (hPL) GOLD Research Grade (25 donors)	100 mL
HPL-601B-150	Human Platelet Lysate (hPL) GOLD Clinical Grade (150 donors)	100 mL
HPL-601B-25	Human Platelet Lysate (hPL) GOLD Clinical Grade (25 donors)	100 mL
HPL-601J-150	Human Platelet Lysate (hPL) GOLD Clinical Grade (150 donors)	30 mL
HPL-601J-25	Human Platelet Lysate (hPL) GOLD Clinical Grade (25 donors)	30 mL
HPL-602J-480	Human Platelet Lysate (hPL) PLATINUM Research Grade (480 donors)	30 mL
HPL-602U-480	Human Platelet Lysate (hPL) PLATINUM Research Grade (480 donors)	180mL

What is the difference between Research Grade and Clinical Grade?

Both products hPL are available for research and clinical purposes. hPL Platinum is a next generation platelet lysate that contains an even higher concentration of growth factors, so its composition is different. A Platinum clinical grade version will be released soon and test material is already available. For most cells, both hPL Gold and hPL Platinum can be used. For optimal selection of hPL, we recommend validating both products with your cells.

Choice of media

The choice of basal medium depends on your application, duration of cell culture and the medium supplements used. For hPL Gold, the use of DMEM/F-12, RPMI-1640, Ham's F-12 and IMDM is advised. We advise against combining hPL Gold with DMEM or alpha-MEM. If the use of DMEM or MEM is required, use of a basal media without CaCl₂. If not possible, hPL Platinum might be a better fit.

hPL Platinum has been validated for use with DMEM, MEM, αMEM, DMEM/F-12, Ham's F-12 and IMDM. Other basal media should be tested for your purpose.

Quality

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Our partnering blood establishment has developed a new method that effectively yields growth factor-rich supplement from excess platelet concentrates. This method removes platelet residue and lowers fibrinogen concentration, eliminating the need for heparin during cell culture. The new method and resulting hPL allow for optimal use of blood donations and contribute to the development and production of promising cell therapies.

Blood donation in the blood establishment is done exclusively by voluntary, non-remunerated donors who give their explicit consent. Donations are always used according to what is included in the informed consent. Risk behavior of donors is questioned and donations are extensively tested according to (inter)national quality requirements for transfusion. Platelet concentrates are treated with pathogen inactivation, reducing the risk of viral and bacterial transmission.

hPL does not contain any animal products and they are not used during preparation so is classified as xeno-free.

Concentration

Typically, hPL can be added to basal medium at 5% to 10% (v/v). In some situations, this can be reduced even further. However, for the optimal choice, it is always recommended to set up a validation comparing different concentrations.

Shelf life

hPL can be stored for at least 2 years at -80°C. We recommend aliquoting the hPL upon receipt in volumes suitable for you to avoid unnecessary freeze-thaw steps.

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 can happen following aggregation by hemagglutinins, 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 until fully thawed in a 37°C water bath.

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2. Prepare complete MSC culture medium by adding [Human Platelet Lysate Solution](#) to basal medium (i.e. Dulbecco's Modified Eagles Medium-F12; DMEM-12) with 2 mM L-glutamine and 100 U/mL Penicillin/streptomycin as final concentration. Filter the complete medium.
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.

Shipping

Product ships frozen on dry ice.

Literature

- Delabie W, De Bleser D, Vandewalle V, De Prest M, Vandekerckhove P, Compennolle V, Feys HB. [The Impact of Amotosalen Photochemical Pathogen Inactivation on Human Platelet Lysate](#) Curr Stem Cell Res Ther. 2024 in press
- De Korte D, Delabie W, Feys H, Klei T, Larsen R, Sigurjónsson Ó, Sousa AP. [Towards standardized human platelet lysate production in Europe: an initiative of the European Blood Alliance](#) Vox Sang. 2024 Jan;119(1):79-87.
- Delabie W, De Bleser D, Vandewalle V, Vandekerckhove P, Compennolle V and Feys H. [Single step method for high yield human platelet lysate production](#) Transfusion. 2023 Feb;63(2):373-383.

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 platelet lysate 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 or manufacturing use only. Not for therapeutic or diagnostic use.

Support

Life Science Production is a division of Life Science Group Ltd.
Life Science Production is [ISIA Traceability Certified](#)
Life Science Group Ltd is an ISO 9001:2015 Certified company

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