

## Human Platelet Lysate-*Customised*

### Product Description

Human Platelet Lysate (hPL)-*Customised* is a xeno-free (animal component-free), made-to-order cell culture supplement. hPL-*Customised* is designed to meet the requirements of your experiments. It is custom-manufactured according to selected parameters (detailed below), whereby all criteria will be kept strictly confidential and will solely be used to manufacture your medium.

hPL is generally suited to support cell expansion from research, through clinical trials to commercial use. hPL-*Customised* is manufactured within a standardized production process and is derived from human platelets obtained from healthy blood donors at licensed blood centres.

hPL-*Customised* meets the small-scale process development needs of biopharmaceutical life cycles, protein therapeutics, biologics, vaccine expression and small-volume testing prior to GMP scale-up.

### Specifications

hPL-*Customised* is a cell culture supplement derived from human Platelet Rich Plasma (PRP) that is subjected to a freeze-thaw process to induce growth factor 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.

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

## Donor Qualification and Testing

hPL-*Customised* 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.

## Tailored Parameters

hPL-*Customised* is custom-manufactured according to selected parameters to meet your specifications. All criteria will be kept confidential.

### Potential blood donor-related parameters:

- Blood donors' age
- Blood type
- Blood donors' gender

### Potential production process-related parameters:

- Number of donor units
- Number of freeze-thaw cycles
- Type of utilised additive solution, e.g. plasma or Platelet Additive Solution (PAS)
- Choice between pooled or aphaeresis-derived platelet concentrates
- Possible usage of pathogen-reduced donor units

## Product Information

Product Code	Product Description	Pack Size
HPL-CUS-100B	Human Platelet Lysate- <i>Customised</i>	100mL
HPL-CUS-100A	Human Platelet Lysate- <i>Customised</i>	500mL
HSUP-001M	HPL Supplement - Heparin (5.000 U/mL)	0.5 mL
HSUP-XF-001M	HPL Supplement – Xeno-free Heparin - (12.5mg/mL)	0.5 mL

*NOTE: To avoid coagulation of the complete culture medium, heparin should be added (see protocol below for details). Due to the custom nature of this product, cost and lead times will vary depending on the exact requirements and blood donor availability.*

## Quality

Each batch of hPL (off-the shelf product) 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-Customised* can be used at a variety of concentrations, from 10% in basal media to as little as 2.5%.

## Protocol for use (adding hPL and heparin to the final culture medium)

1. Thaw *hPL-Customised* overnight at 4°C or for 1 hour in a 37°C water bath.
2. Prepare complete MSC culture medium by adding *hPL-Customised* 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. To avoid coagulation add **Heparin** at a concentration of 2 U/mL **Heparin**, or 0.024 mg/mL **Xeno-Free Heparin** of the complete MSC culture medium. DO NOT add the Heparin directly to the Human Platelet Lysate Solution.
6. Complete MSC culture medium can be stored at 4°C and is stable for approximately four weeks.

## 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.

## 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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