

## Human Platelet Lysate for cell therapy research



## Rapid *cell expansion* with high quality human platelet lysate

#### Reliable and consistent supply

Over the last several years, human platelet lysate (HPL) has emerged as a superior, effective substitute for fetal bovine serum as a culture medium supplement. HPL contains all the growth factors and cytokines necessary which maximizes cell expansion without the need to worry about animal-based supplements or lot-to-lot variability. HPL is an excellent xeno-free supplement for cell therapy and regenerative medicine applications.

Our manufacturing and supplier network offers reliability and consistency in product supply that customers have come to expect. Captivate Bio's preferred partners meet industry standards for quality, purity, and regulatory compliance.

As a scientific solutions provider focused on emerging markets, including cell-based therapies, we are positioned to provide consistent, high-quality cell culture products to accelerate research and discovery in life science research.



## Human platelet lysate provides *unparalleled* cell growth

Platelets play an important role in tissue repair and wound healing within the body. The growth factors and cytokines naturally found in platelet-rich plasma are contained within extracted platelet lysate solution. HPL is an effective, high-protein supplement for the expansion of a multitude of human cell types, including mesenchymal stem/stromal cells (MSCs), endothelial cells (ECs), T cells, and more.

Captivate Bio offers a broad portfolio of HPL products which enables unparalleled cell growth for stem cells and is among one of the most cost effective and natural way of growing cells. Human platelet lysate is currently available in research and clinical grades, as well as pathogen inactivated and gamma irradiated formats.

#### Superior cell growth and proliferation

In both research and clinical applications, HPL is often used as an alternative to FBS or human AB serum, exhibiting superior cell growth. Although FBS is a valuable supplement enriched with nutrients such as hormones, plasma proteins, growth factors, fibronectin, and laminin, the associated risk factors with using animal-derived supplements have raised awareness to stop its use as a growth supplement. HPL has emerged as an efficient alternative to FBS with increased proliferation which enables sufficient production of cells for potential cell therapy applications. Sample data below shows HPL outperforming FBS and AB serum in the culture of hMSCs.



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# HPL can support the growth and proliferation of cells in culture, as platelets are known to play a vital role in tissue renewal and wound healing.

Mohamed et al. The Korean Journal of Hematology. 2020. Blood Res 2020; 55(1): 35-43.

# Reduce *time*, cost and variability of your cultures

#### Platelet sourcing and testing

#### **Platelet collection**

Human platelet origin refers to the country or region in which the raw blood was collected, and is not to be confused with the country in which the finished product was processed. With all human platelet lysate products, the country of origin is stated on the certificate of analysis that you receive with your product.

#### **Quality control testing and traceability**

To ensure traceability of supply, human donor platelets are obtained from AABB accredited, US FDA registered blood centers, as well as platelets obtained from healthy blood donors at licensed blood centers in the EU. All platelets are tested for infectious diseases using criteria for transfusable blood products.

#### **Fibrinogen-depleted**

Fibrinogen depletion is an additional step completed during the platelet manufacturing process in order to remove all fibrins. Fibrinogen depletion decreases the presence of unwanted clotting that is sometimes present in HPL even when heparin is added. This procedure can decrease the concentration of growth factors and deplete coagulation factors and adhesive proteins.

#### **Gamma irradiation**

Gamma irradiation is a powerful treatment to further reduce the risk of adventitious viruses present in serum or blood products. Treatment with gamma-irradiation is typically conducted at 25-40kGy in order to safely eliminate pathogens and inactivate viruses, all while maintaining its optimal efficacy. Gamma irradiation complies with the highest safety guidelines for clinical applications and the production of cellular therapy products.

#### **Pathogen inactivated**

Pathogen-Inactivated HPL is derived from human platelets that have undergone an approved pathogen inactivation process, in order to reduce the risk of transfusion-transmitted infection including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease. Our pathogen-inactivation process uses a photochemical treatment with ultraviolet light to inactivate any potential pathogens and contaminants within the platelet components.

### Cell culture supplements that grow more reliable and consistent outcomes

Captivate Bio offers a large portfolio of HPL products which enables unparalleled cell growth for stem cells and is among one of the most cost effective and natural ways of growing cells.



#### Product recommendation chart

#### Human Platelet Lysate - Superior Alternative to FBS

Customer need	Entry-level, low-priced HPL, new user looking to swap out animal sera for low-risk applications	General stem cell applications using common cell types (MSCs, iPSCs)	Low protein, low endotoxin, extensive quality testing and analysis	Clinically-relevant applications requiring virus-inactivation, safe, efficient cell growth
Benefits	Affordable Rapid cell growth Animal-free	High performance Xeno-free, heparin-free US FDA DMF	High performance Xeno-free and/or heparin-free US FDA DMF	Highly safe Virus-inactivated US FDA DMF
Typical use	Academic research	Pre-clinical research	Cell manufacturing	Cell manufacturing
	Human or animal cells	Stem cell research	Cell therapy research	Clinical research
Recommended	ELAREM™ Prime	PLTGold®	PLTMax®	ELAREM™ Ultimate-FDi
products	PLTMax®	ELAREM™ Perform-FD	PLTGold®	PLTGold® PI

\*Recommendations are provided as an informational guide only, we encourage testing and validating media and supplements based on cell type and application. Please contact our Customer Service team to request a sample.

PRODUCT Human Platelet	source	RUO	GMP	FDA DMF	TOTAL PROTEIN	REQUIRES HEPARIN	ENDOTOXIN (EU/ML)	OSMOLALITY (MOSM/KG)	MYCOPLASMA	PLATELET TESTING	CELLULAR KINETICS	VIRAL INACTIVATION	STERILITY TESTING
ELAREM™ Prime	EU origin	•	-	-	-	Yes	•	•	•	•	•	-	•
EL AREM™ Perform-ED	US origin	•				No	•		•			_	
	05 origin	•	•	•		110	•	•	•	•	•		•
PLTMax®	US origin	٠	•	٠	4.0 - 6.5 g/dL	Yes	٠	٠	٠	٠	٠	-	•
PLTGold®	US origin	٠	٠	٠	4.0 - 6.5 g/dL	No	٠	•	•	٠	•	•	•
Specialty Human Platelet Lysate													
ELAREM™ Ultimate-FDi Gamma-Irradiated	US origin	-	٠	٠	4.0 - 8.0 g/dL	No	٠	•	٠	٠	•	•	•
PLTGold® Pathogen-Inactivated	US origin	-	•	٠	4.0 - 6.5 g/dL	No	٠	•	٠	•	•	٠	٠

#### Product selection guide

\*Table is provided for information purposes only and includes standard quality tests; please refer to the product's Certificate of Analysis for specific product results.

#### Heparin vs. Heparin-free HPL

Human platelet lysate may retain many of the clotting factors found in raw platelets which can trigger a clot-like reaction when supplemented in cell culture media. Adding a small concentration of heparin, an anticoagulant, minimizes clotting during cell expansion. Heparin-free human platelet lysate is manufactured without any xenogenic components and no anticoagulant is needed.

#### Animal-free HPL products

#### **ELAREM™** Prime

RUO-grade | Requires heparin | 50 mL and 500 mL

Cat. # PR10611 and PR11011

ELAREM<sup>™</sup> Prime is a cost-effective, animal serum-free cell culture supplement based on human platelets that allows researchers to easily transition their cells into an animal serum-free environment. ELAREM Prime provides the same growth factor benefits as FBS, with better cell proliferation and expansion. Since ELAREM<sup>™</sup> Prime contains fibrinogens, an anticoagulant (or Heparin) at a final concentration of 0.024 mg/mL should be added to avoid coagulation.

Platelets are derived from donors collected at EU blood collection centers.

#### **ELAREM™** Supplement

Xeno-free anticoagulant | 0.5 mL

Cat. # SU10210

ELAREM<sup>™</sup> Supplement is a xeno-free and preservative-free anticoagulant that prevents clotting of human Platelet Lysate in cell culture medium during cell expansion.

#### **PLTMax**®

RUO- and GMP-grade | Requires heparin | 100 mL and 500 mL

#### Cat. # RUO = PLTMAX100R and PLTMAX500R GMP = PLTMAX100GMP and PLTMAX500GMP

PLTMax® is widely and globally used as a manufacturing component in the generation of adult stems cells in Phase I to Phase III clinical trials. Using PLTMax, clinicians from North America, Europe, South America, the Middle East, Asia and Australia have produced stem cells for therapeutic indications in neurology, nephrology, gastrointestinal disease, wound repair and cardiology. Since PLTMax® contains certain plasma components such us fibrinogen and coagulation factors, an anticoagulant (or Heparin) must be added to the cell culture media to avoid clotting.

Platelets are derived from donors collected at US blood collection centers.





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#### Xeno-free and heparin-free HPL products

#### **PLTGold**®

RUO- and GMP-grade | 100 mL and 500 mL | DMF available

Cat. # RUO = PLTGOLD100R and PLTGOLD500R GMP = PLTGOLD100GMP and PLTGOLD500GMP

PLTGold® Human Platelet Lysate is a Xeno-Free cell culture supplement that is a superior alternative to fetal bovine serum (FBS) for use in human mesenchymal stem cell cultures. PLTGold is an unfractionated product derived from human platelets that does not require the addition of heparin. Optimal growth of MSCs can be achieved with 5% PLTGold. PLTGold been used to effectively to grow mesenchymal stem cells derived from other species including mouse, rabbit and porcine.

PLTGold Human Platelet Lysate is derived from normal human donor platelets collected at U.S. blood centers. Multiple donors units are pooled in large batch sizes and manufactured to produce a consistent product.

Platelets are derived from donors collected at US blood collection centers.



#### **ELAREM<sup>™</sup> Perform-FD**

RUO- and GMP-grade | 50 mL, 100 mL and 500 mL

Cat. # RUO = PE20612, PE20812 and PE21012 GMP = PE20622, PE20822 and PE21022

ELAREM<sup>™</sup> Perform-FD is a fibrinogen-depleted human platelet lysate. Due to the fibrinogen-depletion process, ELAREM<sup>™</sup> Perform-FD does not require anticoagulant addition. Each batch of ELAREM<sup>™</sup> Perform-FD is produced from large pools of platelet units to ensure batch-to batch consistency and enable reproducible conditions.

Platelets are derived from donors collected at US blood collection centers.



#### Viral-inactivated and heparin-free HPL products

#### **ELAREM<sup>™</sup> Ultimate-FDi**

GMP-grade | 50 mL, 100 mL and 500 mL | DMF available

Cat. # UL40622, UL40822 and UL41022

ELAREM<sup>™</sup> Ultimate-FDi is a virus-inactivated and fibrinogen-depleted human platelet Lysate of US origin, suited for clinical trials and therapeutic cell development needs. ELAREM<sup>™</sup> Ultimate-FDi combines excellent cell performance rates and a high safety level, both necessary for industrial in vitro cell expansion. ELAREM<sup>™</sup> Ultimate-FDi is manufactured, tested and released in compliance with the relevant GMP guidelines. The final product is gamma-irradiated at a dose of 25~40 kGy in order to comply with the highest safety guidelines for clinical applications.

Due to the fibrinogen-depletion process, ELAREM<sup>™</sup> Ultimate-FDi does not require the addition of heparin, however, trace amounts of xeno-free heparin may be present in the human platelet Lysate.

Platelets are derived from donors collected at US blood collection centers.



#### **PLTGold® Pathogen-Inactivated**

GMP-grade | 100 mL and 500 mL | DMF available

Cat. # PLTGOLD100GMP-PI and PLTGOLD500GMP-PI

PLTGold®-PI is a non-xenogeneic, animal serum-free product derived from human platelets that have undergone an approved pathogen inactivation process. PLTGold®-PI is used as a manufacturing component in the generation of adult stem cells.

Platelets are derived from donors collected at US blood collection centers.



Related cell culture media and reagents

Captivate Bio offers the most common cell culture media, matrices, and supplements which are designed to promote cell growth, proliferation, and maintenance of a variety of cell types.

#### **Cell Culture Media**

Products include DMEM/F12, RPMI 1640, as well as DMEM, MEM, and customer-specific formulations, as well as other serum-free media and custom media manufacturing services which are produced on-demand.

#### **Cell Culture Reagents**

Captivate Bio offers high quality buffers and salt solutions (DPBS and HBSS) that are manufactured within the United States. Each lot includes pH, endotoxin, osmolality, mycoplasma testing, and sterility testing per USP 71 guidelines.

#### **Biomatrices**

Captivate Bio offers a new portfolio of a chemically defined cell adhesion-promoting microenvironments offered as pre-coated cultureware. These extracellular matrix coatings mimic adhesion proteins such as vitronectin, laminin, and fibronectin. The myMATRIX<sup>™</sup> portfolio of ready-to-use and animal component-free biomatrices promote cell expansion of human iPSCs and MSCs in serum-free and xeno-free media. The screenMATRIX<sup>™</sup> is a rapid, 96-well plate coated with a variety of extracellular microenvironments which helps identify the optimal culture environment based on cell type.

For additional product or technical information, please visit www.captivatebio.com, email orders@captivatebio.com, or call customer service at (617) 607-4017.

#### Frequently Asked Questions

#### What is the difference between research-grade and clinical-grade HPL?

Both grades are manufactured under the same conditions and follow the same protocols. Depending on the manufacturer, each grade of HPL may have different testing and batch record documentation. Please refer to the product's Certificate of Analysis or contact our Customer Service team for additional information.

#### Do we need to add Heparin when using HPL?

Heparin is an anti-coagulant used to decrease clotting and/or prevent clots in blood products. We offer several grades of HPL (RUO and GMP) as well as heparin-required and heparin-free HPL.

The PLTMax® and ELAREM<sup>™</sup> Prime brands do require the addition of Heparin, all other HPL offered by Captivate Bio are heparin-free.

#### What type of quality testing is available for HPL?

In addition to the standard testing of donor material for infectious diseases, every lot of human platelet lysate is tested for biochemical properties, bacterial and fungal contamination, mycoplasma, endotoxin, and cell growth. Please refer to the products Certificate of Analysis for specific tests and results.

#### **References and Publications**

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# Your research is our purpose

Captivate Bio specializes in the development and delivery of innovative cell culture tools and reliable US-based media manufacturing services to the research, therapeutic, and healthcare communities at an affordable price to all.

We are obsessively passionate about the possibilities of cellular technologies and in our ability to empower researchers with the scientific tools to create a better world.

Let's create captivating science, together.



#### Together, we make breakthroughs happen.

#### Captivate Bio

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