Pathogen Inactivated PLTMax<sup>®</sup> & PLTGold

Human Platelet Lysate with the Longest Clinical Experience! EVOLVING WITH YOU!

#### Pathogen Reduced Human Platelet Lysate

PLTMax<sup>®</sup> and PLTGold<sup>®</sup> were originally obtained for transfusion in humans and therefore meet all the requirements of the FDA and

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AABB, including testing for transmissible diseases. However, the inherent risk of emerging infectious agents from human blood products remains a concern for the efficient production of large volumes of cells for applications in cell therapy. For that reason, we have developed pathogen inactivated versions of our successful products: PLTMax<sup>®</sup>-PI and PLTGold<sup>®</sup>-PI.

### Outstanding customer support

**Mill Creek Life Sciences** is dedicated to meeting the customer's needs. We offer high quality hPL media supplements and invaluable technical service to help customers grow and flourish in the ever changing world of cell therapy.

## Effective for use with MSCs

**PLTMax**<sup>®</sup>-**PI** and **PLTGold**<sup>®</sup>-**PI** are manufactured with human platelets that have undergone the INTERCEPT<sup>®</sup> pathogen reduction process, by Cerus Corporation. Using PI products to grow MSCs will yield similar performance to regular **PLTMax**<sup>®</sup> and **PLTGold**<sup>®</sup>, with an approved pathogen reduction process.

ADIPOGENESIS PLTGold<sup>®</sup> PLTGold<sup>®</sup>-PI OSTEOGENESIS PLTGold<sup>®</sup> PLTGold<sup>®</sup>-PI







Mill Creek Life Sciences provides the tools and technologies to support the development and application of cellular and biologic therapeutics. Mill Creek technology was licensed from discoveries at Mayo Clinic, one of the world's leading non-profit medical centers. Mayo Clinic's Rochester campus is located adjacent to Mill Creek Life Sciences. Both organizations are committed to discovering and applying innovative approaches to patient care.



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# Effective with MSCs

Pathogen reduced hPL

Master File with the FDA

Manufactured under cGMP in large batches to reduce lot-to-lot variation

Increased cell growth kinetics versus serum-based supplements

Great for generating cells in large scale bioreactors



# Pathogen Inactivated PLTMax<sup>®</sup> & PLTGold<sup>®</sup> MILL CH

# About PLTMax<sup>®</sup> and PLTGold<sup>®</sup> Pathogen Inactivated (PLTMax<sup>®</sup>-PI and PLTGold<sup>®</sup>-PI)

PLTMax<sup>®</sup>-PI human platelet lysate is an animal serum-free product derived from human platelets. PLTMax<sup>®</sup>-PI is intended for use as a media supplement in ex vivo cell culture during the manufacture of cell, gene, and tissue-engineered products (ancillary materials). A Master File for PLTMax<sup>®</sup>-PI is registered with the FDA and is cross-referenceable. Contact us for more information on the MF.

PLTGold®-PI human platelet lysate is a non-xenogeneic, animal serum-free product derived from human platelets. PLTGold®-PI is intended for use as a media supplement in ex vivo cell culture during the manufacture of cell, gene, and tissue-engineered products (ancillary materials). A Master File for PLTGold®-PI is registered with the FDA and is cross-referenceable. Contact us for more information on the MF.

PRODUCT	CATALOG #	SIZE	
PLTMax <sup>®</sup> -PI Clinical Grade (GMP)	PLTMax27GMP-PI	27mL	
	PLTMax100GMP-PI	100mL	
	PLTMax500GMP-PI	500mL	
	PLTMax1000GMP-PI	1,000mL	
PLTGold <sup>®</sup> -PI Clinical Grade (GMP)	PLTGold27GMP-PI	27mL	PLTMax: PLTGold
	PLTGold100GMP-PI	100mL	CLINICAL CRADE PARTICIDENT NATURATION MENTODENT NATURATION MENTODENT MENT
	PLTGold500GMP-PI	500mL	
	PLTGold1000GMP-PI	1,000mL	

#### **Safety Information & Precautions**

- Products not intended for direct use in animals or humans.
- All PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI donors have been tested for infectious diseases. In addition, the collected platelets are subjected to pathogen reduction using the INTERCEPT<sup>®</sup> Blood System for Platelets prior to receipt, transport, and use in manufacture of hPL. However, as a blood derived product, PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI should be handled and treated as potentially infectious.
- Universal precautions for handling and disposal of biological products should be used when working with PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI.

#### Using PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI

- Thaw at 37°C or 4°C.
- It is not recommended to expose PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI to repeated temperature changes that could affect the integrity of its components. For that reason, we recommend thawing the product and preparing aliquots as soon as it is received.
- Aliquots can be stored at -20°C or colder protected from light. Storage at 4°C is recommended for periods no longer than 2 weeks.
- Complete media can be prepared, aliquoted and stored at -80°C for up to 9 months. Do not store complete media at 4°C for longer than 2 weeks.
- Some turbidity and/or protein aggregates may appear with PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI. This is normal due to the nature of the product.

 Filtration of PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI by itself is not recommended. Filtration of complete media containing PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI may be performed, if necessary.

#### Culture Conditions Using PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI

- Cell seeding should be performed following the general guidelines for the specific cell type. For Mesenchymal Stem Cells (MSCs), cells are typically plated at approximately 2x103 – 5x103 cells per cm2.
- For MSCs, PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI can be used at 5% vol/vol in a typical cell culture medium such as DMEM or α-MEM. If the basic media doesn't contain Glutamine, a source of L-Glutamine will need to be added to the media at a final concentration of 2mM. For other types of cells, the concentration of PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI will need to be titrated according to the application (a titration from 2% vol/vol to 10% vol/vol is recommended to establish the percentage of PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI needed for the cell type to use).
- Due to the presence of certain plasma components such us fibrinogen and coagulation factors, the use of **PLTMax®-PI** involves the addition of heparin to the cell culture media at a final concentration of 2U/mL to minimize clotting.
- Do not allow primary MSC confluence to exceed 70-80%.

#### **Particulate Formation**

Particulate formation or clotting in **PLTMax®-PI** is normal. Particulate formation can be minimized by avoiding freeze/ thaw cycles or by preventing extended storage at 4°C. **PLTMax®-PI** shows no loss of function even in the presence of large particulates in the supplement. If a specific application requires minimizing the presence of particulates, filtration may be performed.

#### Origin

 PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI was developed to provide a pathogen inactivated hPL. It is derived from our current product, PLTMax<sup>®</sup>-PI / PLTGold<sup>®</sup>-PI.

**References** (see website for additional references)

- Crespo-Diaz R, Behfar A, Butler GW, et al. Platelet lysate consisting of a natural repair proteome supports human mesenchymal stem cell proliferation and chromosomal stability. *Cell Transplant*. 2011;20(6):797-811.
- Burnouf T, Strunk D, Koh MB, et al. Human platelet lysate: Replacing fetal bovine serum as a gold standard for human cell propagation? *Biomaterials*. 2016 Jan;76:371-87.
- Alonso-Camino V, Clarke B, Nielsen J, et al. In vitro expansion of mesenchymal stem cells using media supplemented with unfractionated heparin-free platelet lysate. Poster presented at: ISCT Annual Meeting. London, UK. 2017 May.