

Gamma Irradiated PLTMax® & PLTGold®

**Human Platelet Lysate
with the Longest
Clinical Experience!**

EVOLVING WITH YOU!



Evolving to meet the changing world's needs

Platelets used in the production of **PLTMax®** and **PLTGold®** were originally obtained for transfusion in humans and therefore meet all the requirements of the FDA and 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 stem cells for regenerative medicine. For that reason, **we have developed gamma irradiated versions of our successful products: PLTMax®-GI and PLTGold®-GI.**

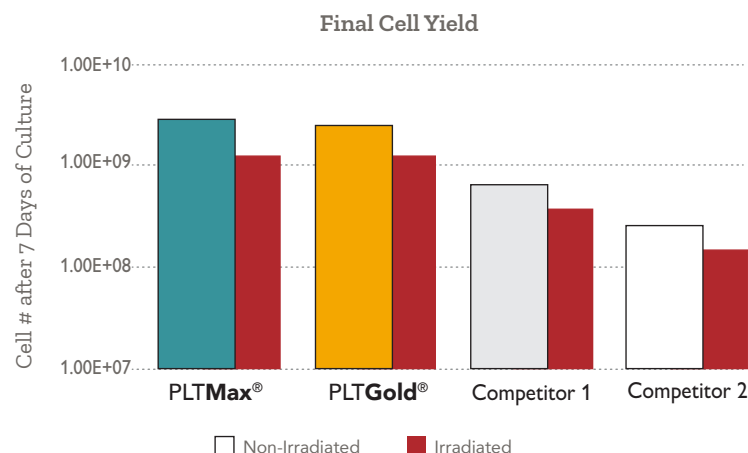
Outstanding customer support

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.

Safer products without compromising performance

Our gamma irradiated products offer an added safety measure with minimal impact on product potency. Average doubling times obtained with both our non-irradiated and irradiated platelet lysates are significantly lower than those obtained by competitors, which gives greater cell yield in a shorter period of time and therefore are more cost effective. The chart below shows the differences in ultimate cell yield* with different hPL products after starting with 10 million cells and using a 7-day growth period.

* Cell yields were calculated using internal data and published competitor cell doubling times.

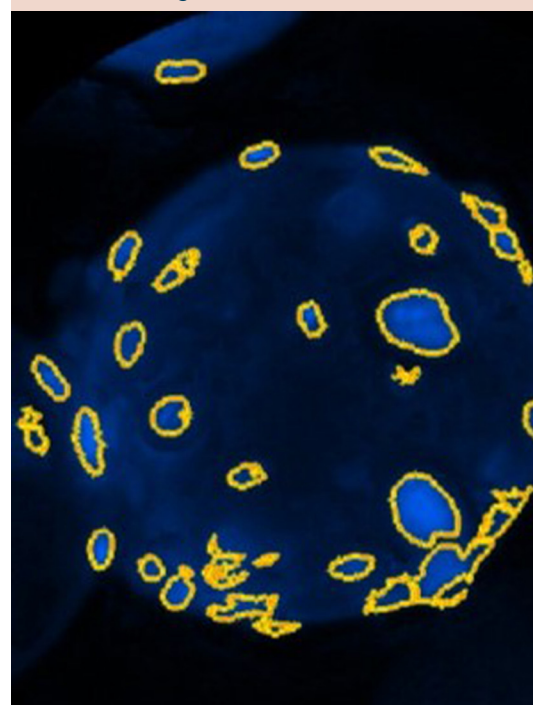


Master File with the FDA

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

Increased cell growth kinetics compared
to other gamma irradiated products
available on the market

Great for generating cells in
large scale bioreactors



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.



Gamma Irradiated PLTMax® & PLTGold®



About PLTMax® and PLTGold® Gamma Irradiated (PLTMax®-GI and PLTGold®-GI)

PLTMax®-GI is an animal serum-free product derived from human platelets. **PLTMax®-GI** is used as a manufacturing component in the generation of adult stems cells. A Master File for **PLTMax®-GI** is registered with the FDA and is cross-referenceable. Contact us for more information on the MF.

PLTGold®-GI is a non-xenogeneic, animal serum-free product derived from human platelets. **PLTGold®-GI** is used as a manufacturing component in the generation of adult stems cells. A Master File for **PLTGold®-GI** is registered with the FDA and is cross-referenceable. Contact us for more information on the MF.

PRODUCT	CATALOG #	SIZE
PLTMax®-GI Clinical Grade (GMP)	PLTMax27GMP-GI	27mL
	PLTMax100GMP-GI	100mL
	PLTMax500GMP-GI	500mL
	PLTMax1000GMP-GI	1,000mL
PLTGold®-GI Clinical Grade (GMP)	PLTGold27GMP-GI	27mL
	PLTGold100GMP-GI	100mL
	PLTGold500GMP-GI	500mL
	PLTGold1000GMP-GI	1,000mL



Using PLTMax®-GI / PLTGold®-GI

- Thaw at 37°C or 4°C.
- It is not recommended to expose **PLTMax®-GI** / **PLTGold®-GI** 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.
- Some turbidity and/or protein aggregates may appear with **PLTMax®-GI** / **PLTGold®-GI**. This is normal due to the nature of the product.
- Due to the turbidity and/or protein aggregates, filtration of **PLTMax®-GI** / **PLTGold®-GI** or complete media containing **PLTMax®-GI** / **PLTGold®-GI** may be performed.

Culture Conditions Using PLTMax®-GI / PLTGold®-GI

- 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®-GI** / **PLTGold®-GI** 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®-GI** / **PLTGold®-GI** 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®-GI** / **PLTGold®-GI** needed for the cell type to use).

- Due to the presence of certain plasma components such as fibrinogen and coagulation factors, the use of **PLTMax®-GI** 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%.

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.
- Staff NP, Madigan NN, Morris J, et al. Safety of intrathecal autologous adipose-derived mesenchymal stromal cells in patients with ALS. *Neurology*. 2016 Nov 22;87(21):2230-2234.
- Aho JM, Dietz AB, Radel DJ, et al. Closure of a Recurrent Bronchopleural Fistula Using a Matrix Seeded With Patient-Derived Mesenchymal Stem Cells. *Stem Cells Transl Med*. 2016 Oct; 5(10):1375-1379.

- Lanzoni G, Linetsky E, Correa D, et al. Umbilical cord mesenchymal stem cells for COVID-19 acute respiratory distress syndrome: A double-blind, phase 1/2a, randomized controlled trial. *Stem Cells Transl Med*. 2021 May;10(5):660-673.
- Boland LK, Burand AJ, Boyt DT, et al. Nature vs. Nurture: Defining the Effects of Mesenchymal Stromal Cell Isolation and Culture Conditions on Resiliency to Palmitate Challenge. *Front Immunol*. 2019 May 10;10:1080.

Safety Information and Precautions

- Products not intended for direct use in animals or humans.
- All **PLTMax®-GI** / **PLTGold®-GI** donors have been tested for infectious diseases. In addition, the final product has been gamma irradiated. However, as a blood derived product, **PLTMax®-GI** / **PLTGold®-GI** should be handled and treated as potentially infectious.
- Universal precautions for handling and disposal of biological products should be used when working with **PLTMax®-GI** / **PLTGold®-GI**.

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