

PLTGold[®] Gamma Irradiated (PLTGold[®]-GI) Product Insert

About PLTGold[®]-Gl

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 Number | Size |
|---|-------------------|---------|
| - PLTGold [®] -GI Clinical Grade (GMP) - | PLTGold27GMP-GI | 27mL |
| | PLTGold100GMP-GI | 100mL |
| | PLTGold500GMP-GI | 500mL |
| | PLTGold1000GMP-GI | 1,000mL |

Safety Information & Precautions

- Products not intended for direct use in animals or humans.
- All PLTGold[®]-GI donors have been tested for infectious diseases. In addition, the final
 product has been gamma irradiated. However, as a blood derived product, 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 PLTGold[®]-GI.

Using PLTGold[®]-Gl

- Thaw at 37°C or 4°C.
- It is not recommended to expose 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 PLTGold[®]-GI. This is normal due to the nature of the product.
- Filtration of PLTGold[®]-GI by itself is not recommended. Filtration of complete media containing PLTGold[®]-GI may be performed, if necessary.

Culture Conditions Using 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, 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 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 PLTGold[®]-GI needed for the cell type to use).
- Do not allow primary MSC confluence to exceed 70-80%.

Origin

 PLTGold[®]-GI was developed to provide a gamma irradiated hPL. It is derived from our current product, PLTGold[®].

References

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- 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.
- Bulur P, Wiltshire T, Dudakovic A, et al. Impact of media supplementation on the secretion of IFN-γ induced indoleamine 2-3 deoxygenase and resultant immune suppression by mesenchymal stromal cells. Poster presented at: ISCT Annual Meeting. Montreal, Canada. 2018 May.
- Alonso-Camino V, Mirsch W. In vitro expansion of human primary endothelial cells for clinical use using EndoGo[™] XF Medium supplemented with PLTGold[®] human platelet lysate. Poster presented at: ISCT Annual Meeting. Montreal, Canada. 2018 May.

Manufacturer:

Mill Creek Life Sciences, LLC, 221 1st Avenue SW, Ste 209, Rochester, MN 55902 USA

For Technical and Ordering Information, Please Contact Us At:

Phone: +1 (507) 287-6257 Email: info@millcreekls.com Website: www.millcreekls.com