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Applications of Cook human platelet lysate in cell therapy

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Introduction

Human platelet lysate (HPL) has emerged as a viable human-derived alternative to fetal bovine serum (FBS) for cell manufacturing for cell-based therapeutics. Derived from human platelets, HPL contains similar growth factors and cytokines found in FBS at comparative levels. Stemulate™ Pooled Human Platelet Lysate is provided in two different versions, a heparin-requiring HPL (PL-H) and a heparin-free HPL (PL-NH), and is produced at an industrial scale (minimum lot size of 20 L), in accordance to GMP standards and proper documentation, from large number of pooled platelets resulting in high lot-to-lot consistency and purity.

Stemulate provides researchers with the ability to incorporate HPL in their early research and development phase through a high quality research grade (both the heparinrequiring version and the heparin-free version) with the ability for a smooth transition into clinical manufacturing using the GMP clinical grade. Preliminary results of both versions of HPL at different concentrations (2.5, 5, and 10%) supported cell proliferation of primary cells such as dermal fibroblasts, endothelial, and mesenchymal stem/progenitor cells such as amniotic-, bone marrow-, and adipose-derived MSCs to comparable levels of FBS at all concentrations.

Stemulate was also shown to support large-scale expansion of MSCs using xeno-free microcarriers in 3D cultures. For more information, visit poster #389, Large-scale expansion of mesenchymal stem cells in 3D cultures using xeno-free microcarriers and human platelet lyesate. Stemulate-based freezing media maintained high cell viability and normal biological properties of neonatal and adult MSCs from various tissues post-thaw, and was comparable to serum-free freezing media and FBS containing freezing media. These studies show the ability of using Stemulate as an alternative to FBS for the growth of primary and various neonatal and adult stem cells derived from various tissues and for large-scale expansion in 2D and 3D cultures for cell-based therapeutics, as well as a freezing and recovery solution.

Applications of Stemulate in cryopreservation of neonatal and adult stem cells. For more information, visit poster #352: Freezing and recovery of mesenchymal stem



Figure 1: Post-thaw viability of adipose-derived MSCs frozen in different cryopreservation solutions

 Stemulate-based freezing solutions and culture media containing Stemulate maintained high viability of adipose-derived MSCs post thaw.



- Figure 3: Post-thaw viability of bone marrow-derived MSCs frozen in different cryopreservation solutions
- Stemulate-based freezing solutions and culture media containing Stemulate maintain high viability of bone marrow-derived MSCs post thaw.

Applications of Stemulate in cell recovery. For more information, visit poster #352: Freezing and recovery of mesenchymal stem cells in human platelet lysate.



- Figure 4: Post-thaw viability of amniotic membrane-derived MSCs frozen in different cryopreservation solutions
- Stemulate-based freezing solutions and culture media containing Stemulate maintained high viability of amniotic membrane-derived MSCs post thaw.

Applications of Stemulate in supporting growth of primary human cells. For more information, visit poster #351: Human platelet lysate supports growth of human skin and vascular-derived cells similar to fetal bovine serum and serum free media.





Figure 6: Growth of HUVECs when FBS is replaced with Stemulate-NH in the bullet kit. Stemulate-NH does not require the addition of heparin to the media.

- Stemulate-NH supports HUVECs growth and proliferation.
 Stemulate-NH can replace FBS from EGM-bullet kit for xe-
- no-free culture of HUVECs.

Applications of Stemulate in supporting growth of neonatal and adult stem cells. For more information, visit poster #291: Comparison of human platelet lysate (HPL) and fetal bovine serum (FBS) for optimal culture conditions of neonatal and adult mesenchymal stem cells (MSCs).



Figure 7: Amniotic membrane-derived MSCs cultured in Stemulate-NH for two passages

- Stemulate-NH supports isolating and establishing amniotic membrane-derived MSCs similar to FBS.
 Low concentrations of Stemulate support the growth
- Low concentrations of Stemulate support the growth and proliferation of amniotic membrane-derived MSCs



Figure 8: Proliferation of dental pulp-derived stem cells established in Stemulate-NH and expanded for several passages in Stemulate-NH or Stemulate-H

Both types of Stemulate (H/NH) support proliferation
 of doptal pulp derived stem cells for several passages



Figure 2: Growth kinetics of fibroblasts post-thaw

 Stemulate-based freezing solutions and culture media containing Stemulate maintain kinetics activity of fibroblasts for several passages post thaw. Figure 5: Growth kinetics of dermal fibroblasts in Stemulate-NH and FBS

- Stemulate-NH supports the isolation and expansion of dermal fibroblasts from human foreskin.
- Low concentrations of Stemulate support proliferation of fibroblasts for several passages.

of dental pulp-derived stem cells for several passages.

Conclusions

- Stemulate has a substantial amount of essential growth factors that are necessary for cell growth and functions.
- Stemulate can substitute for FBS in all products development life cycles of cell therapy products.
- Stemulate allows for xeno-free and large expansion of stem cells and primary cells for clinical applications.
- Stemulate-based cryopreservation solutions can be used to cryopreserve adult and neonatal stem cells and primary cells and maintain high viability and growth kinetic post thaw.