

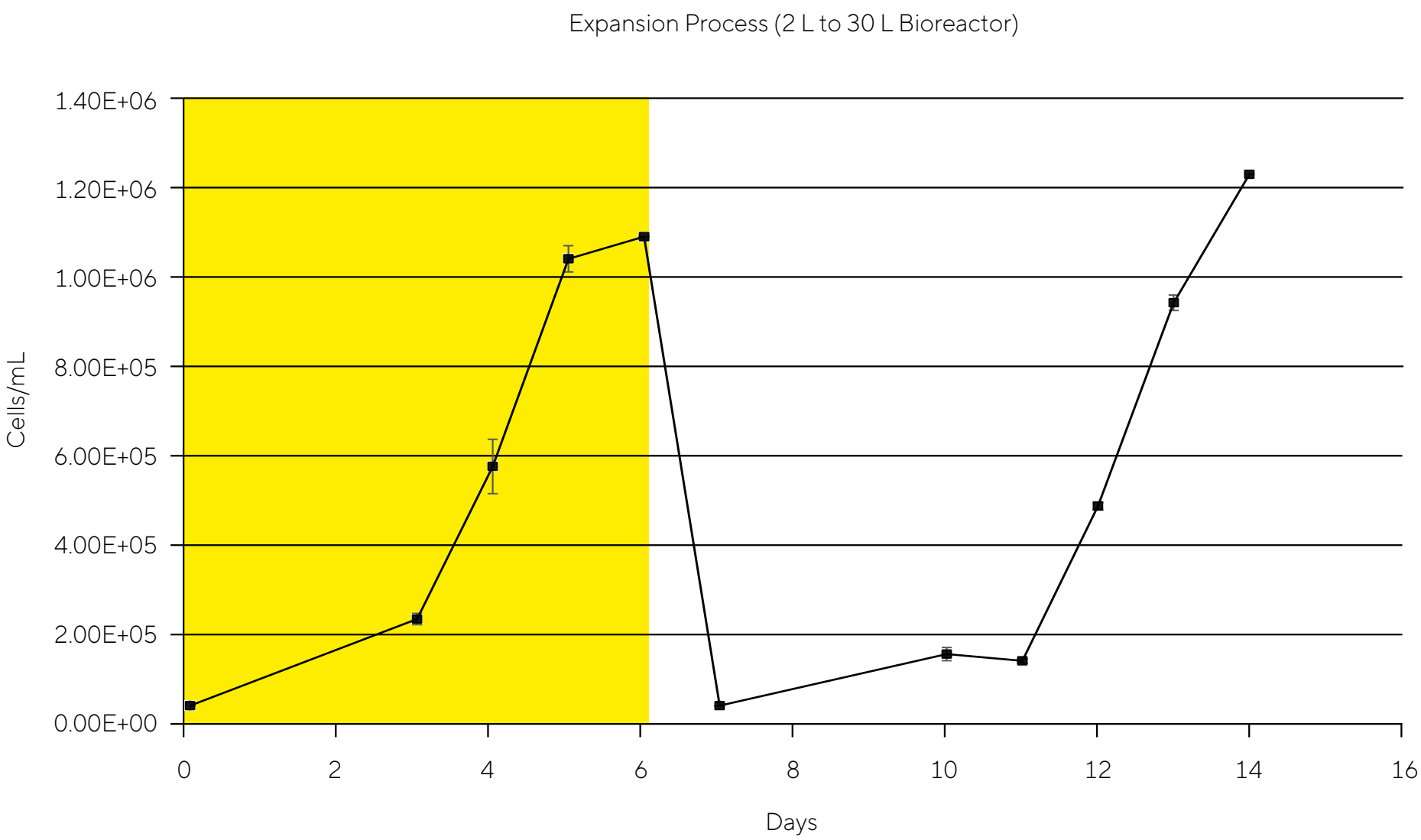
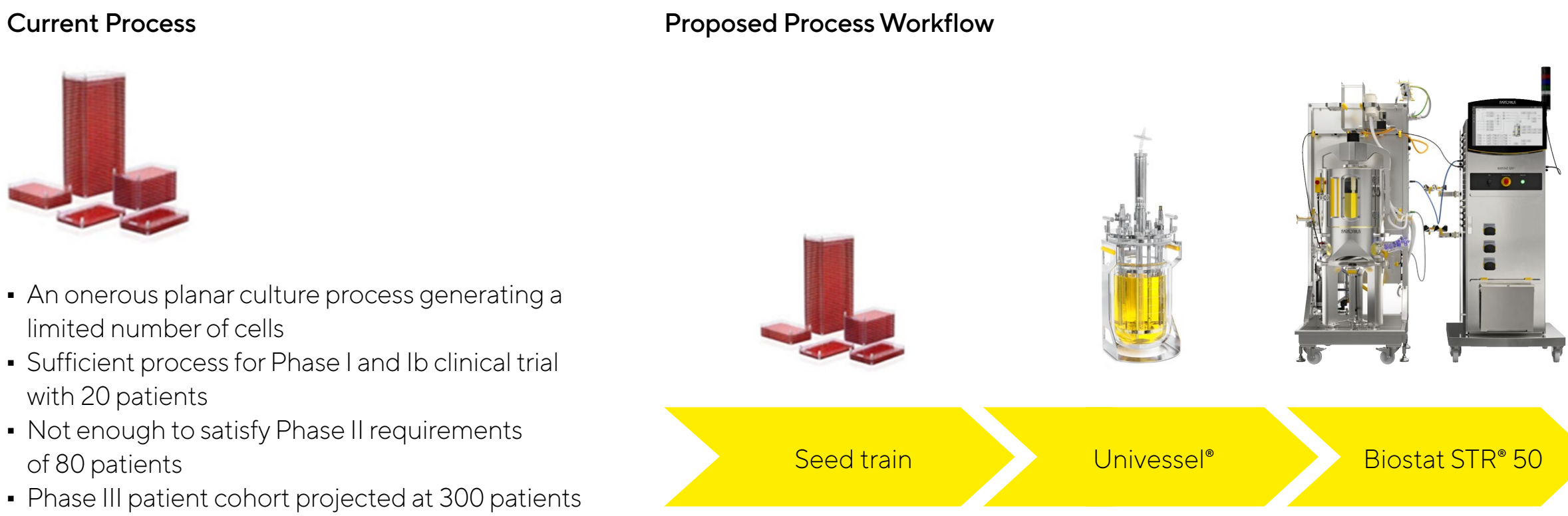
# A Robust, Single-Use Solution for Expansion of Human Mesenchymal Stem Cells in Xeno-Free Medium

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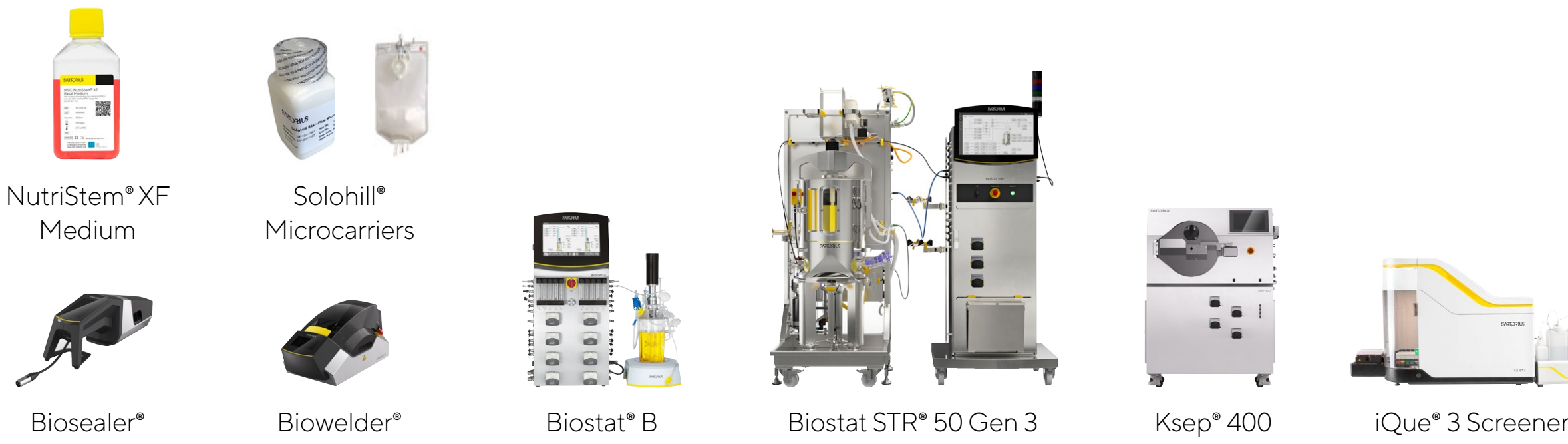
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## Experimental Approach

The objective of this experiment was to expand umbilical cord-derived mesenchymal stem cells (MSCs) on collagen-coated microcarriers (MCs). A seed train, which consisted of a N-1, 2 L Univessel® Glass bioreactor (BR), was used to generate cells to seed a Biostat STR® 50 BR at 30 L. Cells were expanded for 7 days prior to harvest and concentration using the Ksep® 400 centrifuge.



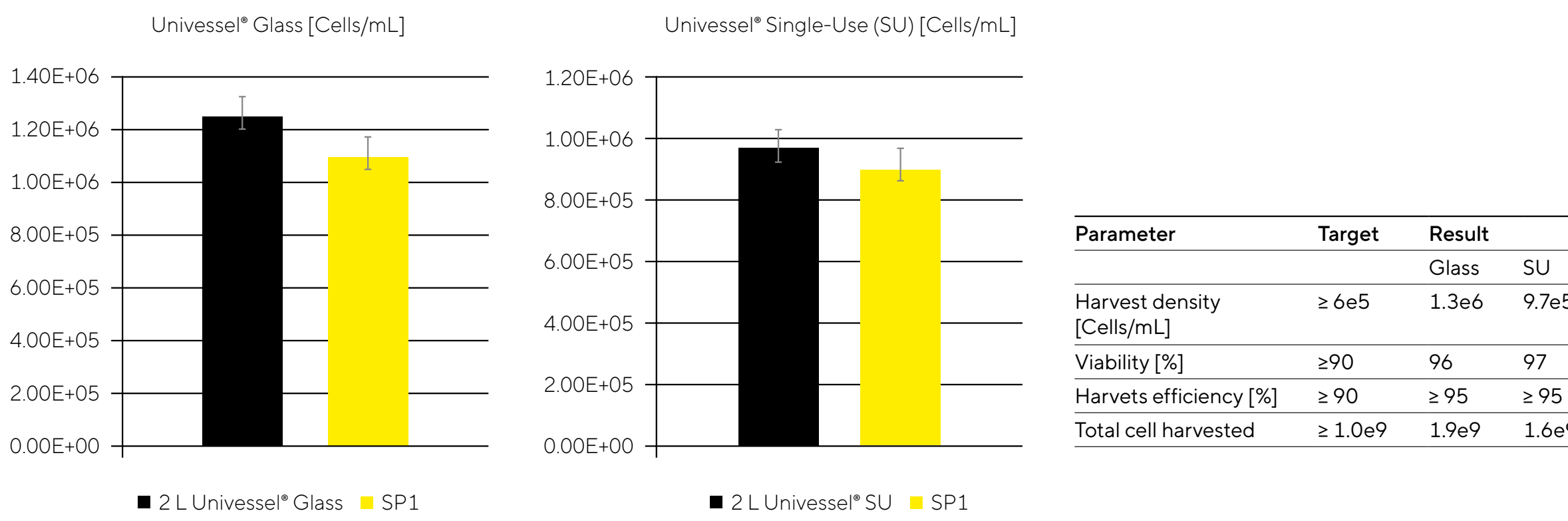
## Materials



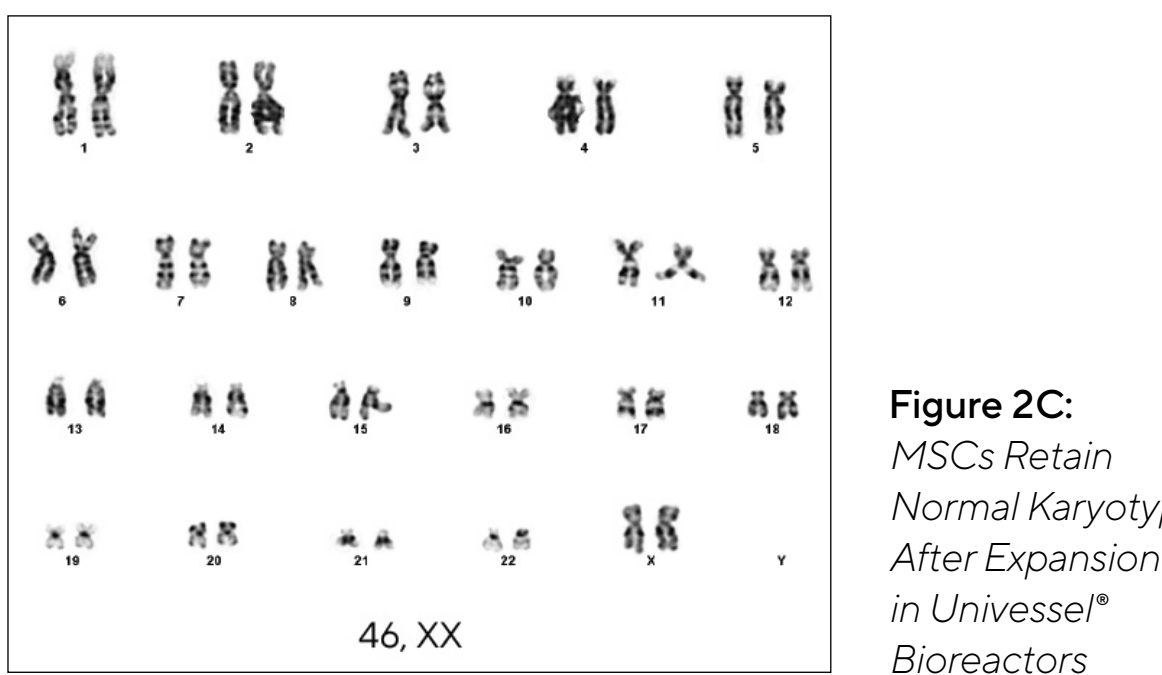
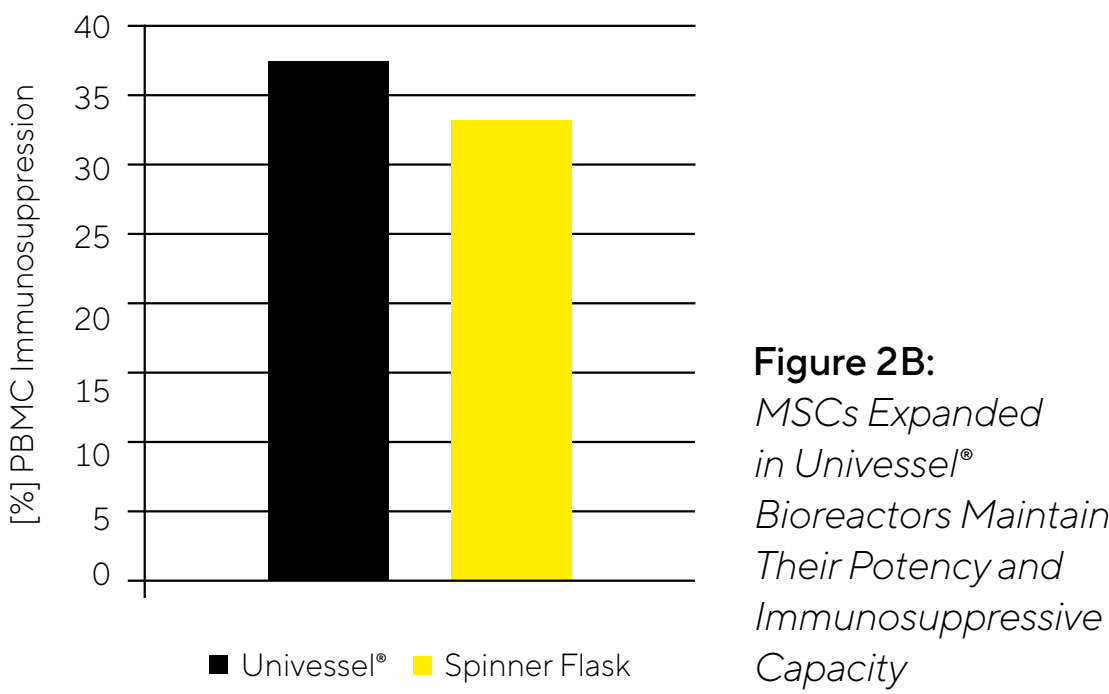
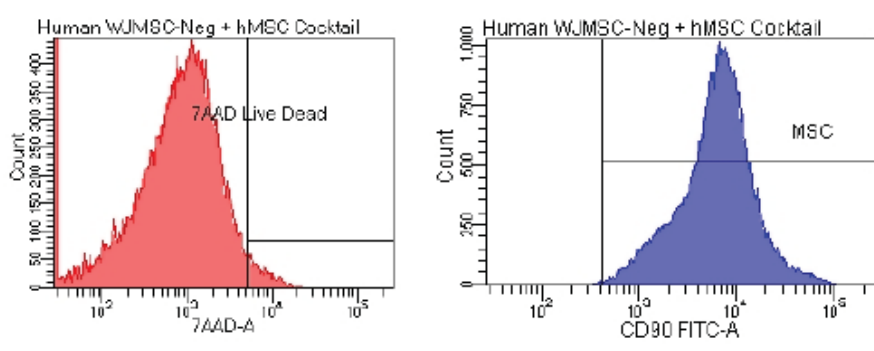
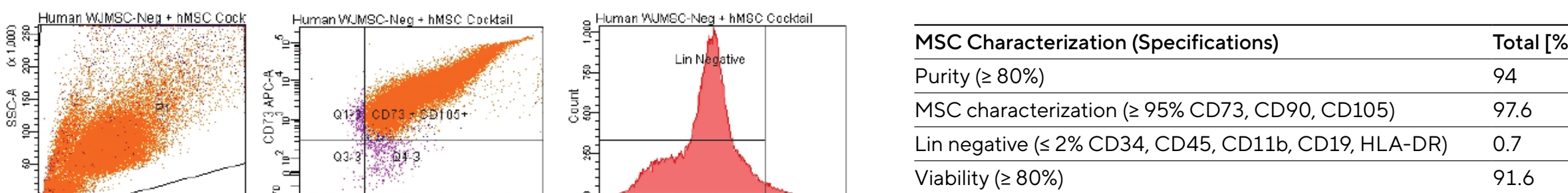
**Figure 1:** Schematic of the Sartorius Pilot and Scale-up Solutions, Including, Biostat® B and Univessel® Glass Bioreactors, MSC NutriStem® XF Medium, Biostat STR® 50 Gen3 Bioreactor, Ksep® 400, Solohill® Collagen-Coated Microcarriers in Microcarrier Delivery Systems (MDS), Biosealer®, Biowelder® and iQue® 3 Flow Cytometer

## Results

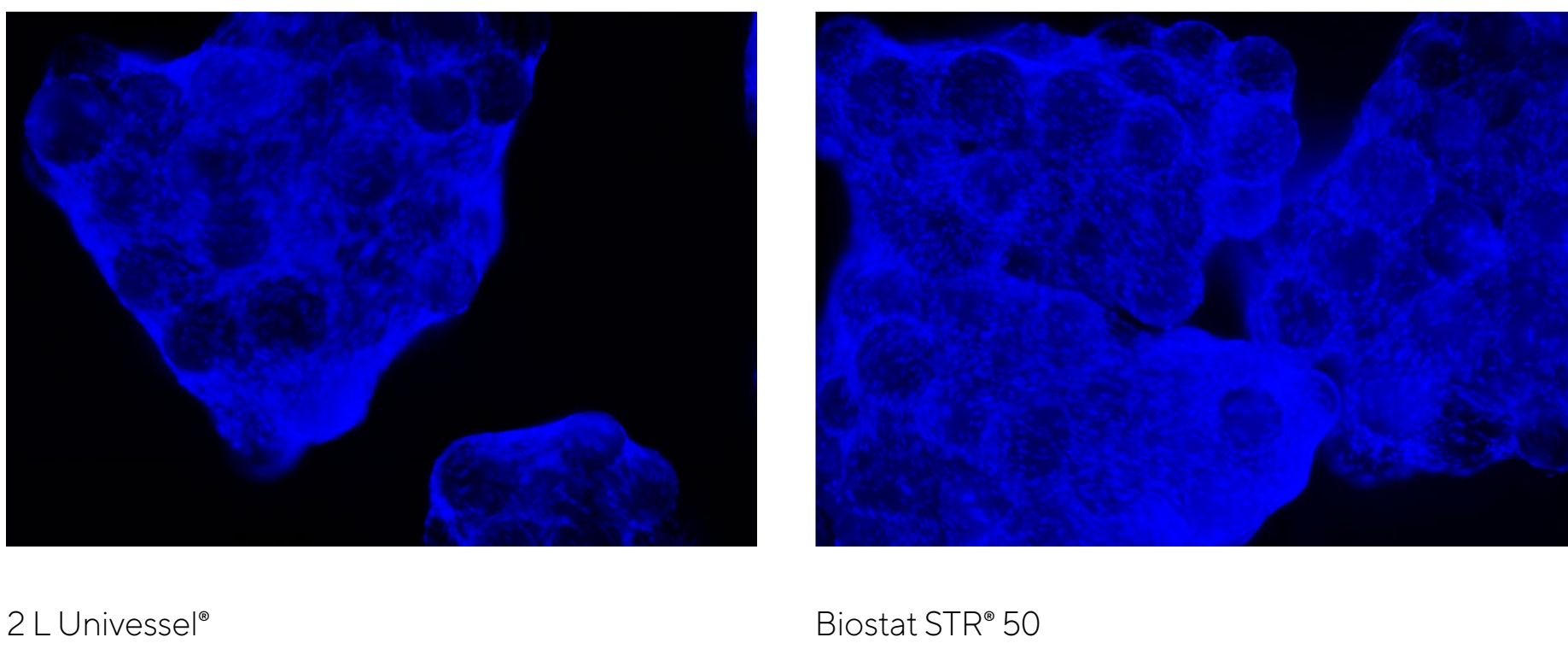
### Optimization of 2 L Bioreactor Process



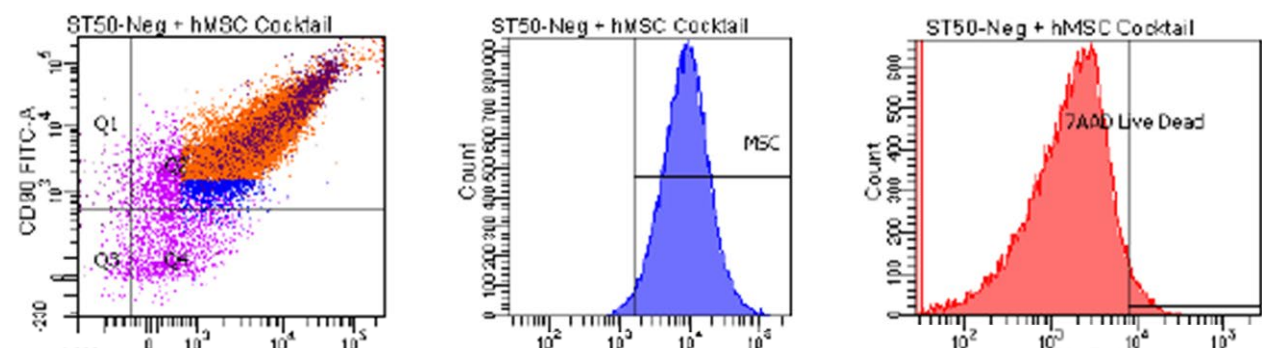
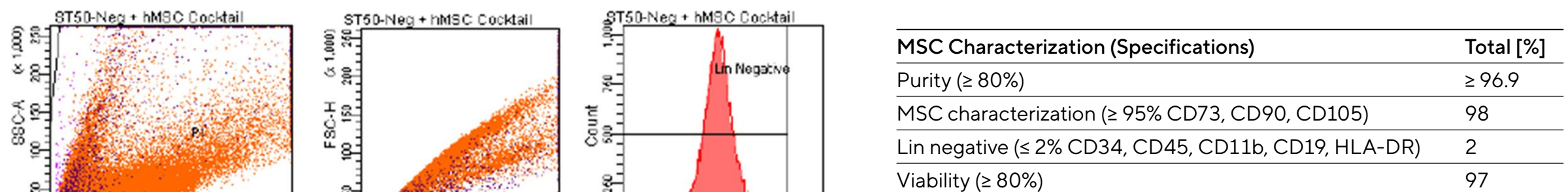
### Characterization of Cells Harvested From Biostat® B 2 L Bioreactors



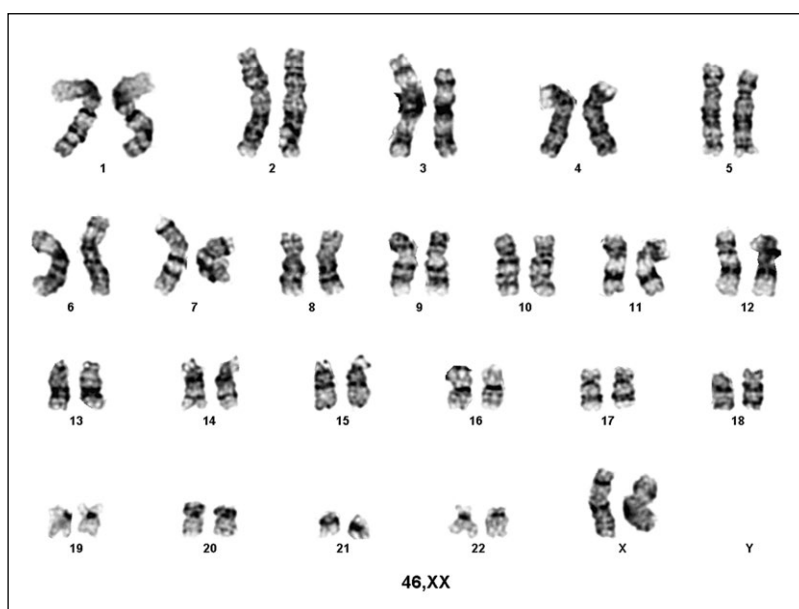
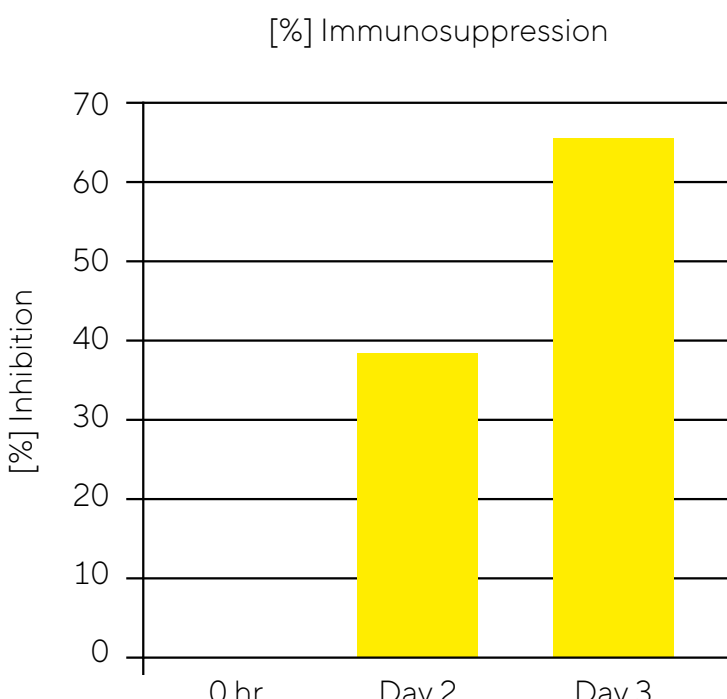
### DAPI Images



### Characterization of Cells Harvested From the Biostat STR® 50 Bioreactor

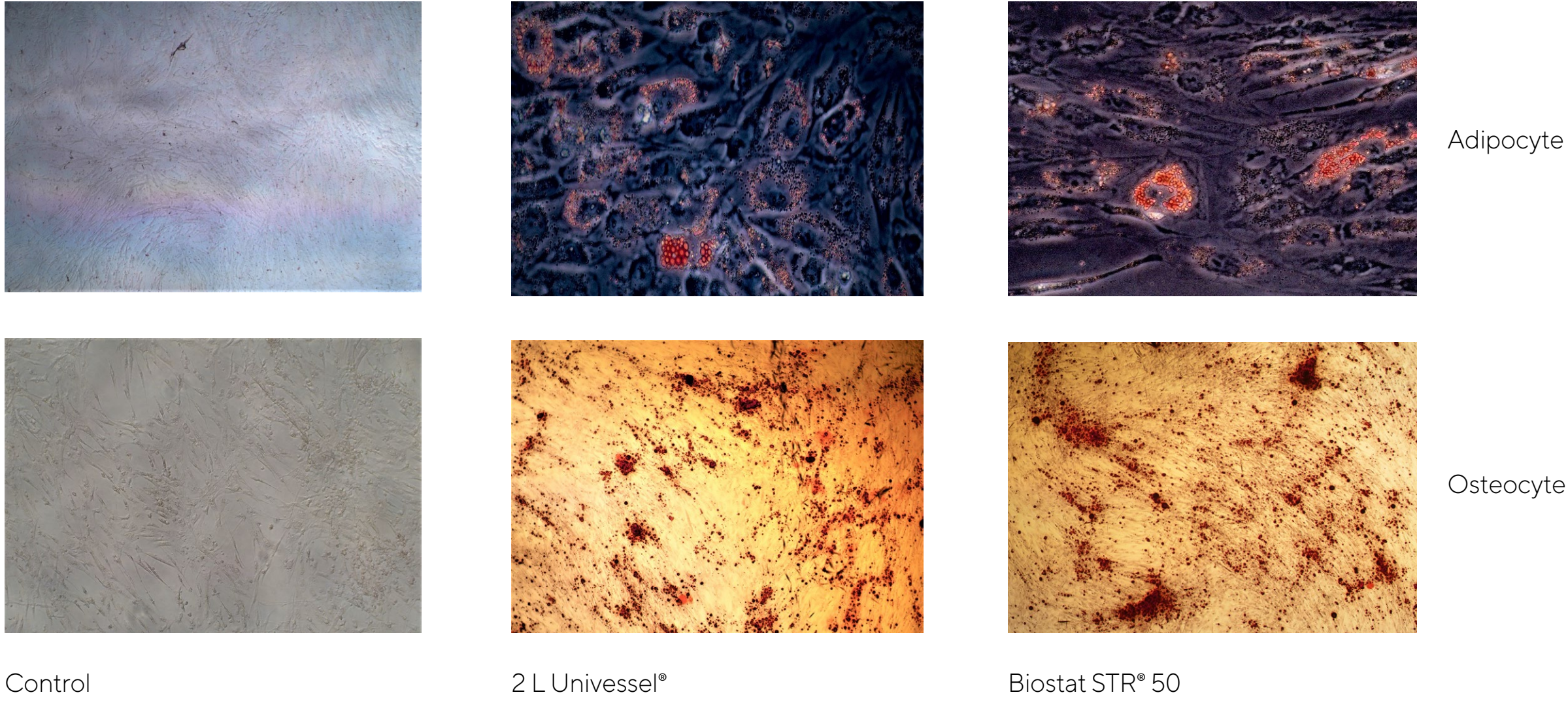


**Figure 4A:** MSC Surface Markers Are Maintained After Expansion in 3D Suspension-Based Culture Systems

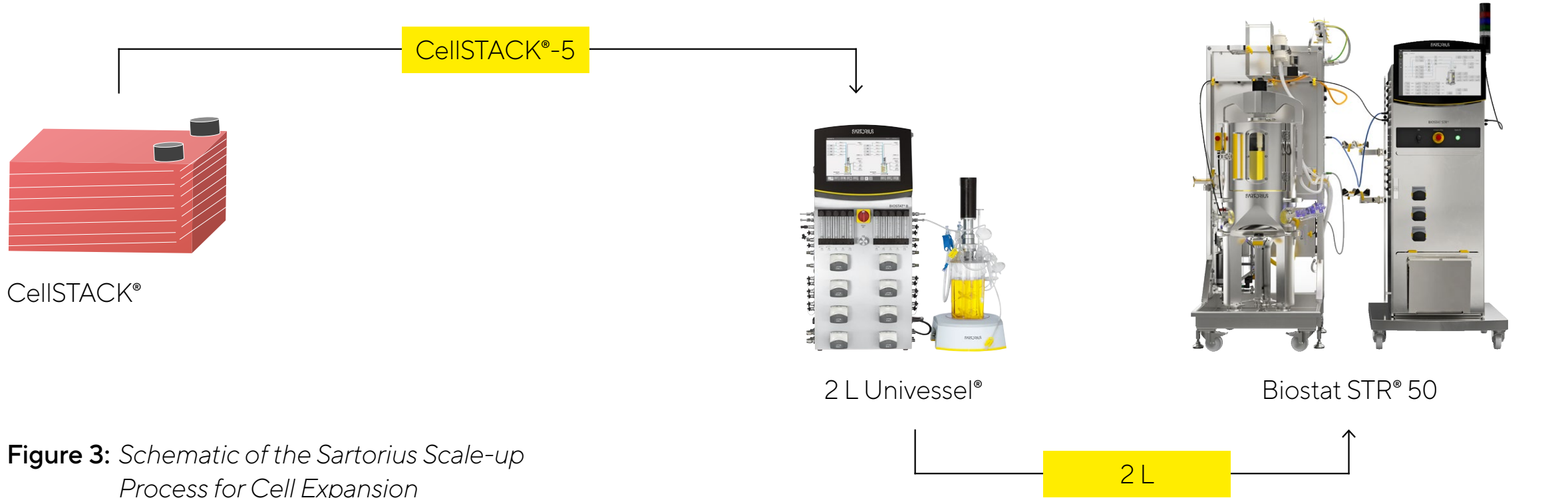


**Figure 4C:** MSCs Retain Normal Karyotype After Expansion in Univessel® Bioreactors

### Multilineage In Vitro Differentiation of MSCs: Osteocyte and Adipocyte Lineages



## Performance of the Scale-Up Process



## Summary

- The Sartorius MSC pilot solution, along with the subsequent MSC manufacturing solution, comprise a scalable offering that provides continuity and enables seamless process transfer for industrialized expansion of adherent cell types
- This study provides proof of concept for the successful transition from a 2D static to a 3D suspension culture process for cell expansion, using Sartorius MSC solutions
- With these solutions, MSCs can be robustly expanded to large working volumes in a simplified seed train. Cells maintain high viability and stem cell relevant critical quality attributes
- Sartorius solutions enabled KUMED to generate enough cells to reach clinical trial goals
- This accelerates time to market and saves on production costs, ultimately leading to increased accessibility and affordability of these life-saving therapies