Simplifying Progress

Maximizing the Potential of Cell Therapy Products With Innovative Biopreservation Solutions

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Abstract

Reliable and effective cell preservation solutions are critical to ensuring timely transport of viable cell therapy products from the manufacturing site to the point of care. However, cell preservation presents several obstacles for the shipping process, including low viability or recovery rates, and poor biocompatibility of current preservation solutions.

To overcome these challenges, we developed various solutions for cell preservation, including cryopreservation for long-term storage of cells intended for clinical applications, hypothermic preservation for cell transport and short-term storage of autologous cell therapy products, as well as recombinant human albumin that improves post-thaw viability and extends the therapeutic window.

Introduction

There are over 3,500 cell therapies in development across a range of therapeutic areas. These cell therapies include CAR-T cells, NK cells, MSCs, and differentiated iPSCs and ESCs, and cover a range of diseases and conditions across fields like oncology, cardiology, neurology, infectious disease, pulmonology, gastroenterology, and immunology. The success of these therapies heavily depends on cell preservation to maintain their viability and functionality. It's critical to use reliable and effective cell preservation solutions to ensure that the cell therapy products remain stable and efficacious throughout the treatment trajectory. The most common approach is to cryopreserve the cells for long-term storage using cryoprotective agents (CPAs) like dimethyl sulfoxide (DMSO), which is permeable and toxic to cells. For applications requiring short-term cell storage of (e.g., therapeutic processes and shipment), cold storage has emerged as an alternate approach to reduce post-freezing necrosis and apoptosis, and eliminate the risk of exposure to toxic CPAs. To address these challenges, we developed cryopreservation solutions that are all-in-one, ready-to-use, chemically-defined, and animal-component-free. NutriFreez® D10 (10% DMSO) and D5 (5% DMSO) solutions are designed for long-term storage, and NutriStor® hypothermic cold storage solution is designed for short-term storage. To address custom preservation needs, we offer cGMP-manufactured Recombumin® recombinant human albumin, which holds several advantages compared to human serum albumin in terms of performance, purity, supply, and regulatory compliance.

Experimental Approach

We cryopreserved or stored various types of cells commonly used in cell therapies (CAR-T cells; iPSCs and ESCs; MSCs) in hypothermic conditions for storage and transportation using all-in-one, ready-to-use cryopreservation solutions – using NutriFreez® D5 and D10 solutions, NutriStor® hypothermic storage solution, or custom preservation solutions containing Recombumin® recombinant human albumin. We then measured cell viability, recovery, proliferation, transduction efficiency, immunophenotype, differentiation potential, and karyotype according to the cell type.

Figure 1: *All-In-One, Ready-To-Use Solutions and Recombinant Human Albumin for Custom Solutions*

Results

1. NutriFreez® D5 and D10 both demonstrate reliable performance in preserving CAR-T cells

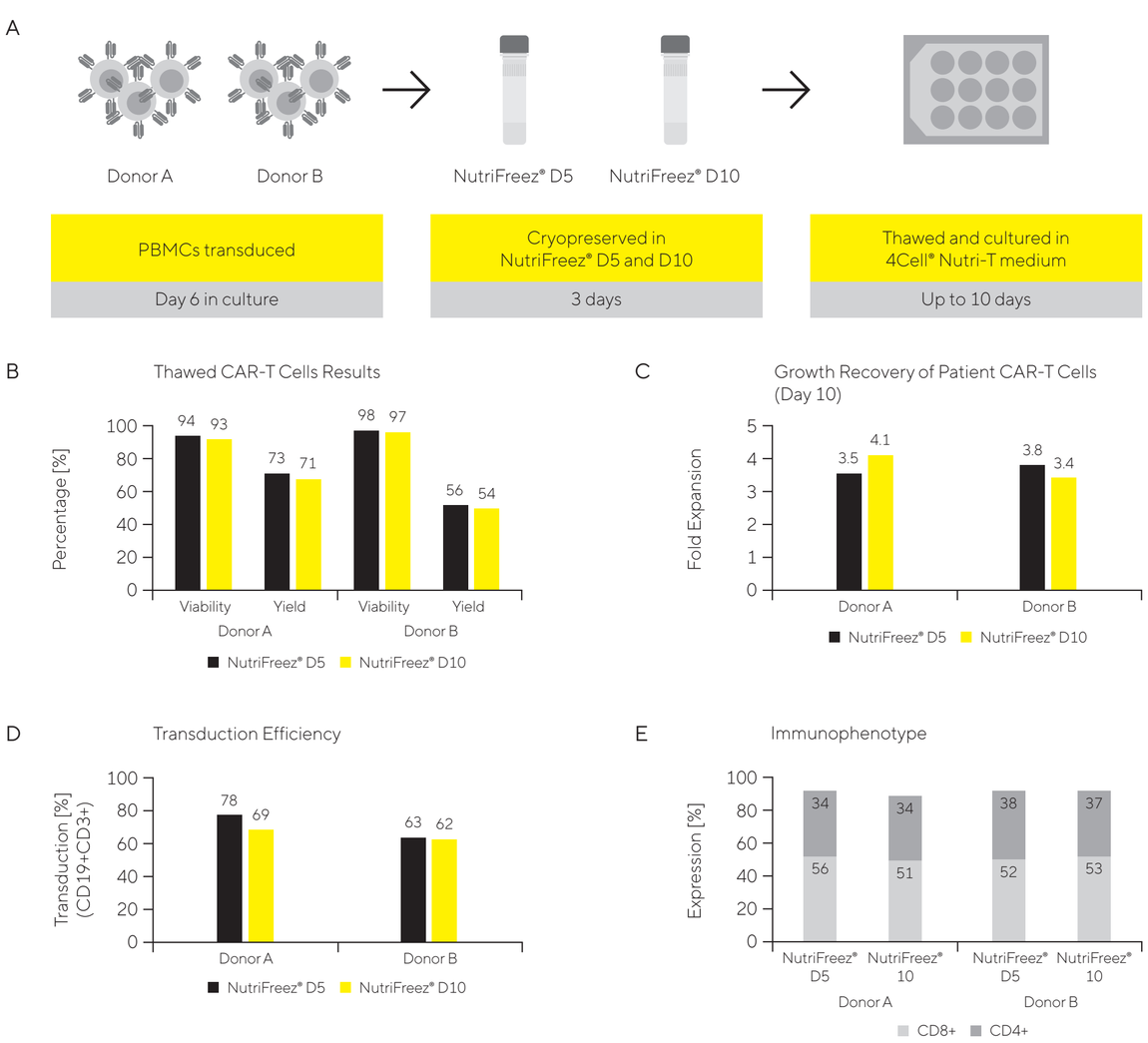

Figure 2: *Experimental Workflow (A), Post-thaw Cell Viability (B), Yield (C), Transduction Efficiency (D), and Immunophenotype (E) Of CAR-T Cells Preserved in NutriFreez® D10 and D5*

2. High viability and recovery of MSCs after cold storage in NutriStor® solution

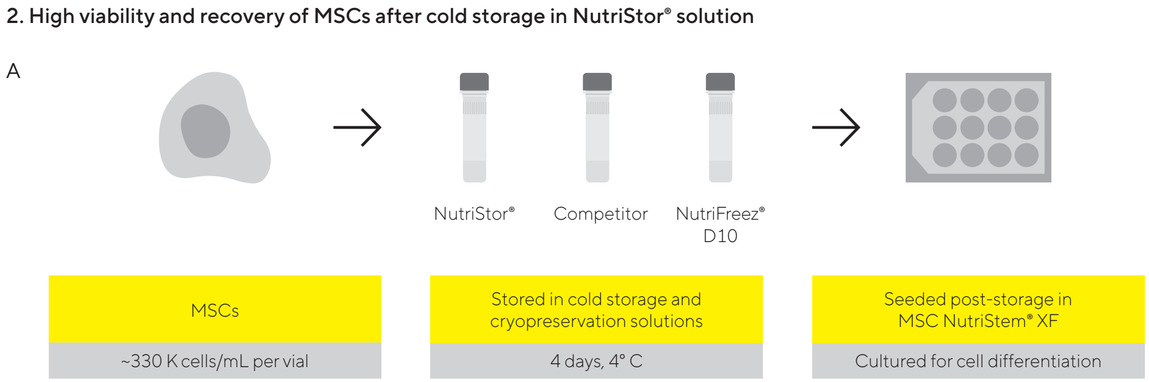

Figure 3: *Experimental Workflow (A), Post-thaw Cell Viability (B), Recovery (C), Differentiation (D), and Karyotype (E) Of MSCs After Cold Storage in NutriStor® Solution*

3. Enhanced iPSCs colony formation after cryopreservation with solutions supplemented with Recombumin® Recombinant Human Albumin

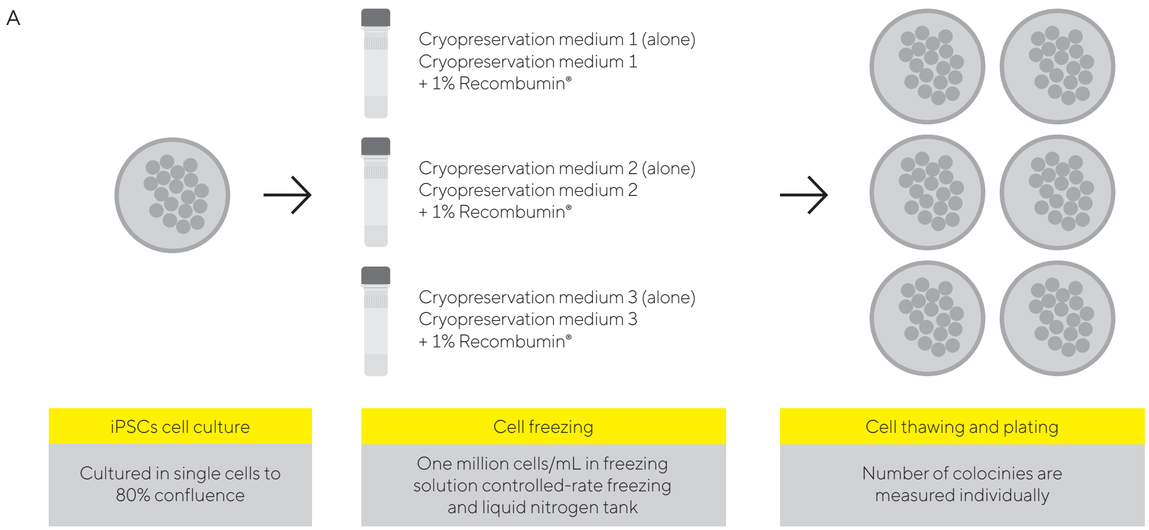

Figure 4: *Experimental Workflow (A) And Colony Formation of iPSCs (B) Post-thaw After Cryopreservation With Solutions Containing Recombumin® Solution*

Conclusion

- NutriFreez® D5 and D10 both keep high post-thaw viability and recovery, preserve cell phenotypes, and simplify cell cryopreservation.
- NutriStor® solution is a suitable alternative to cryopreservation medium for short-term storage and transport of cells, that provides flexibility to your process.
- Recombumin® recombinant human albumin is a versatile stabilizer that outperforms human serum albumin in custom cryopreservation and hypothermic storage solutions.
- You can accelerate your cell therapy products' journey to market with extensive regulatory documentation and support from Sartorius, and ensure a faster route to the clinic.

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