

EVOLVING

THE FUTURE OF CELL THERAPY MANUFACTURING

Cell therapy



Achieving high cell purity with the CTS DynaCollect Magnetic Separation System

Situation

Cell therapy is a rapidly growing industry focused on targeting disease-causing cells and treating immune-mediated diseases. The successful development and manufacture of a cell therapy can result in life-changing treatment and optimizing this process can help support success.

A vital step in cell therapy development is isolating target T cells from white blood cells collected from a patient. These T cells are then transformed downstream into a therapeutic product. The isolation of target cells is carried out using paramagnetic beads that bind to antibodies on the cells of interest, creating a magnetic complex. An instrument with magnetic capabilities is then used to separate the target cells from other white blood cells.

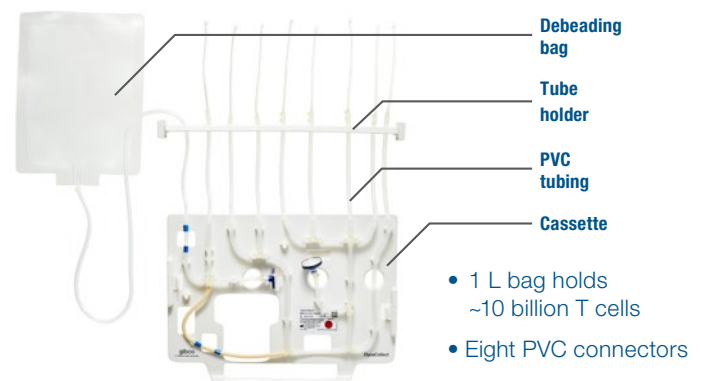
The challenge at this stage of cell therapy development is isolating the right cells quickly and achieving high cell purity so the treatment can be produced and delivered as soon as possible. It is also vital to avoid contamination, impurities, and operator-to-operator variability, especially for autologous therapies, in which cells are returned to the patient. Finding a solution that is rapid, automated, and scalable means cell therapy developers can meet these challenges head-on and accelerate time to clinical and commercial manufacturing. Here we outline the challenges and successes a customer faced when looking to achieve excellent isolation efficiency and high cell purity.

Solution

The customer was provided with the Gibco™ CTS™ DynaCollect™ Magnetic Separation System to try in order to help them improve

cell purity. As a closed, rapid, and fully automated cell isolation and bead removal platform, the CTS DynaCollect system has been designed to address manufacturing challenges in cell therapy. The instrument works with Gibco™ CTS™ Dynabeads™ CD3/CD28 magnetic beads to consistently deliver >85% cell isolation efficiency and 95% purity, with no effect on cell viability. The customer used the CTS DynaCollect system and single-use Gibco™ CTS™ DynaCollect™ Cell Isolation Kit to help isolate target cells at a high purity, minimize failures, and reduce contamination. By streamlining the cell isolation process and reducing the manual steps required, this easy-to-use system helped the customer efficiently achieve high cell purity.

CTS DynaCollect Cell Isolation Kit



Results

The customer initially struggled to reach cell purity levels higher than 40%. To enable maximum cell purity, they were provided with technical guidance and a detailed protocol. Working closely with our technical teams to optimize the use of the CTS DynaCollect system, the customer's isolation efficiency of target cells rose, achieving an average of ~86% across four donors (Figure 1).

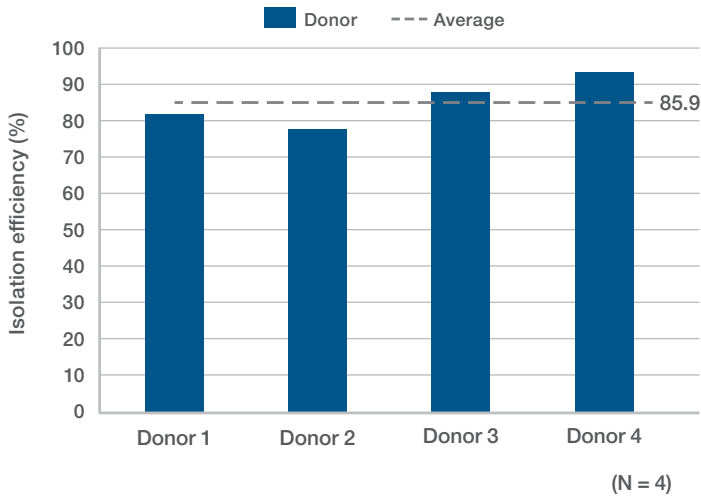


Figure 1. T cells are isolated with robust efficiency obtained with the CTS DynaCollect system and CTS Dynabeads CD3/CD28.

An 85.9% average (79%–94%) isolation efficiency was demonstrated with four healthy donors. (Isolation efficiency was determined by flow cytometry and cell counting of CD3⁺ and CD28⁺ cells.)

When isolating cells for cell therapy production, varying concentrations of different cell types can be present, making the isolation of target cells more difficult. In this case, a high monocyte level of 35.6% proved particularly challenging. Following isolation and activation using the CTS DynaCollect system and CTS Dynabeads CD3/CD28 magnetic beads, the monocyte levels were reduced to 0.1%, enabling the customer to achieve 92.9% cell purity during the third and final run (Figure 2).

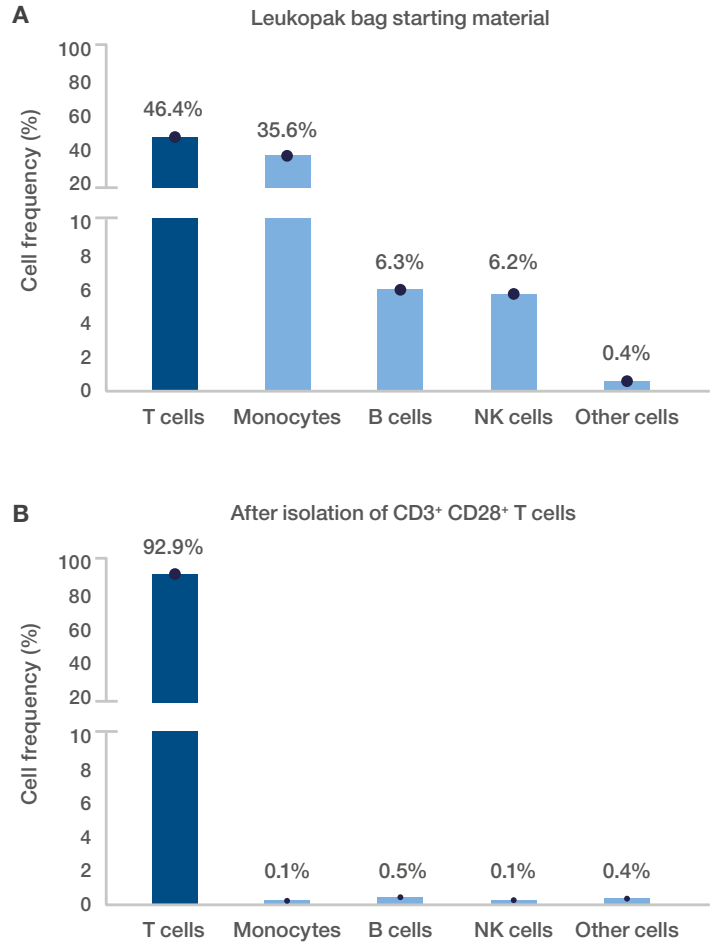


Figure 2. Cell phenotype of starting material and enriched target cells after isolation. (A) Purity of the target cells from unwashed starting material was ~46%. **(B)** After isolation using CTS Dynabeads CD3/CD28 and the CTS DynaCollect Magnetic Separation System, the >92% purity of target cells was achieved.

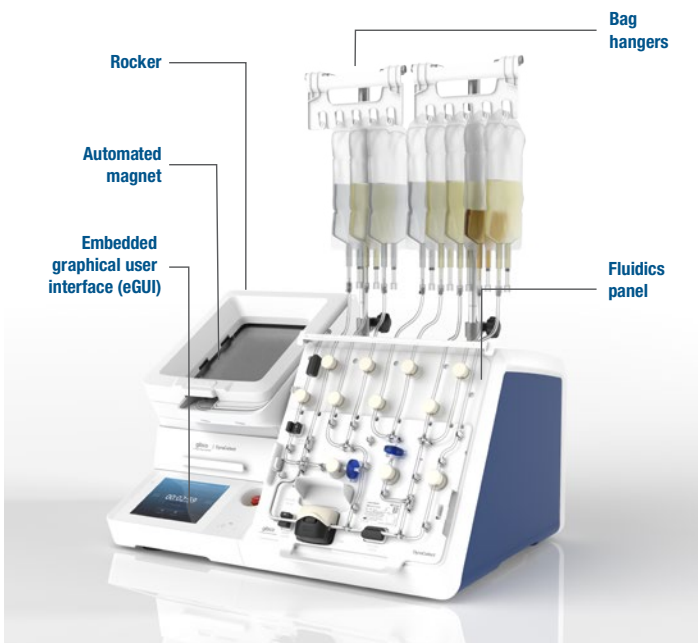
Summary

During the cell isolation trial, the successful optimization of cell purity was supported by:

- A detailed protocol that can be further optimized
- T cell enrichment to reduce monocyte levels
- The proven performance of the CTS DynaCollect system

By combining scalability, flexibility, and automation with rapid performance and modularity, the CTS DynaCollect system integrated into the customer's existing workflow, helping them optimize cell isolation and seamlessly advance their cell therapy development. Thanks to the closed, automated nature of the system, manual handling was greatly reduced, giving the customer confidence in the quality and consistency of their cells. When facing challenges, such as technology transfer, our service-minded, collaborative support can help customers achieve exceptional outcomes. As a result, manufacturers can rely on the CTS DynaCollect system to isolate the correct cells, helping ensure safe and efficacious therapies.

CTS DynaCollect Magnetic Separation System



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