Thermo Físher s c i e n t i f i c



THE FUTURE OF CELL THERAPY MANUFACTURING

Cell therapy

CTS DynaCellect Magnetic Separation System

gíbco

Introduction

The Gibco[™] CTS[™] DynaCellect[™] Magnetic Separation System with touchscreen controls is a flexible, automated, closed system that enables rapid isolation and bead removal for cell therapy manufacturing. Designed to be used with magnetic beads, the CTS DynaCellect Magnetic Separation System delivers exceptional cell recovery, purity, high throughput, process flexibility, and enables the system to easily scale with your process from research through clinical manufacturing without sacrificing cell viability.

Benefits

- Isolation efficiency, purity, and viability—enables >85% isolation efficiency of target cells with >95% purity with no effect on cell viability
- **Processing time**—isolate cells in 70–100 min with Gibco[™] CTS[™] Dynabeads[™] CD3/CD28
- Reproducibility-coefficient of variation (CV) of 3%
- **Process flexibility**—user-programmable software enables you to create and optimize a broad range of protocols
- Modular-use independently or as part of your workflow
- Research through commercial manufacturing—the closed single-use kits enable sterile processing, and an Open Platform Communications Unified Architecture (OPC UA) interface enables connectivity to a 21 CFR Part 11–compliant system

Specifications

The CTS DynaCellect Magnetic Separation System is manufactured in a state-of-the-art cGMP, ISO-certified facility to help ensure the highest quality and consistency for reproducible results. See Figures 1–3 for representative results.

Efficiency	>85% isolation	
Reproducibility	CV of 3%	
Purity	95% (with CTS Dynabeads CD3/CD28)	
Viability of cells	Unaffected	
Isolation scale	Maximum working volume of 1,000 mL (equivalent to ~10 ¹⁰ T cells as input)	
Bead removal scale	Unlimited (verified up to 10 L)	

CTS DynaCellect Cell Isolation Kit

The Gibco[™] CTS[™] DynaCellect[™] Cell Isolation Kit is specifically designed for the isolation and activation of immune cells in cell processing applications.

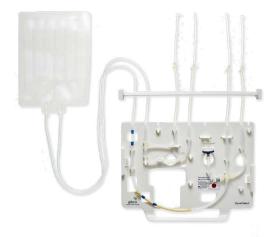
- Maximum capacity: 1,000 mL
- Enables isolation to be done in a class C cleanroom
- 8 weldable lines for input and output bags: DEHP-free PVC (150 mm, 2.4 mm ID, 4.0 mm OD)
- Sterile air filter: 0.20 µm
- Gamma sterilized



CTS DynaCellect Bead Removal Kit

The Gibco[™] CTS[™] DynaCellect[™] Bead Removal Kit is specifically designed for bead removal from immune cells for cell processing applications.

- Continuous processing
- Enables bead removal to be done in a class C cleanroom
- 4 weldable lines for input and output bags: DEHP-free PVC connections (150 mm, 2.4 mm ID, 4.0 mm OD)
- Sterile air filter: 0.20 µm
- Gamma sterilized



CTS DynaCellect software

The CTS DynaCellect Magnetic Separation System comes with two protocols: isolation and bead removal. Protocols can be customized through the intuitive user-programmable interface to create and manage all instrument actions:

- Engage or disengage the magnet
- Open or close the pinched valves
- Change the pump speed (~2-300 mL/min)
- Change the specified volume of the pump
- Change the rocker angle (-30° to 30°)
- Change the rocker speed (1-30 cpm)
- Change the air pressure sensor (maximum 2 bar)

Additionally, the software is easily locked, so that when you are ready to move your optimized process to manufacturing, users can no longer adjust the process settings. The clinical manufacturing mode also includes an optional software module that supports the following features:



- Enables compliance with 21 CFR Part 11
- Ready for DeltaV[™] communication via OPC UA
- Able to provide a summary file (sample ID, run ID, single-use consumable lot, bead lot, operator, date)
- Prepared for barcoding through the USB port

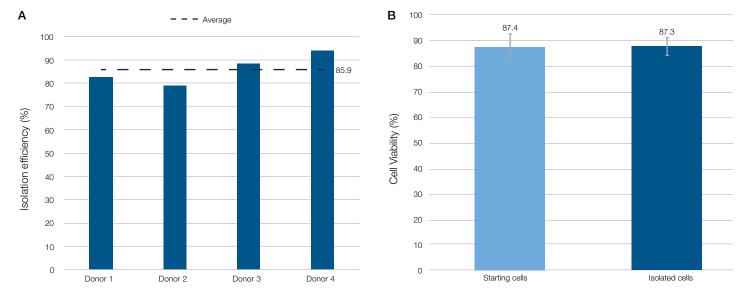


Figure 1. Strong isolation efficiency with no impact on viability of the cells. Using CTS Dynabeads CD3/CD28 and the CTS DynaCellect Magnetic Separation System, (A) isolation efficiency was greater than 85% (n = 4) and (B) viability of the cells was maintained at ~87%, as determined by flow cytometry.

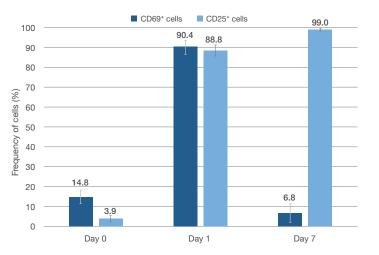
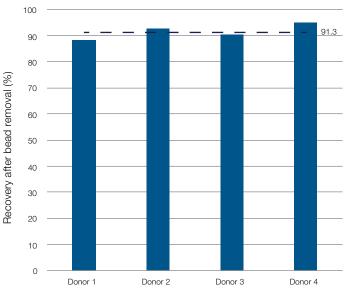


Figure 2. Activation of isolated target cells is confirmed. On day 1, early activation marker CD69 is expressed on target cells and is downregulated by day 7. Late activation marker CD25 is expressed on day 1 and continues to be upregulated and expressed by day 7. Expression profile adheres to expected target cell kinetics (n = 4).



- - - Average

Figure 3. Bead removal process achieves high recovery of cells. Recovery after CTS Dynabeads CD3/CD28 removal was >91% (n = 4). Recovery was assessed by cell counting before and after bead removal at day 7.

Ordering information

Product	Quantity	Cat. No.	
CTS DynaCellect Magnetic Separation System + SmartStart Orientation at installation + 2-year warranty with planned maintenance (PM) in second year	1	A55867	
 CTS DynaCellect Magnetic Separation System + SmartStart Orientation at installation + Installation qualification (IQ) and operational qualification (OQ) + 2-year AB Qualification with OQ post PM and/or repair 	1	A55868	
CTS DynaCellect Cell Isolation Kit	5 pack	A52300	
CTS DynaCellect Bead Removal Kit	5 pack	A52301	

Learn more at thermofisher.com/dynacellect

For Research Use or Manufacturing of Cell, Gene, or Tissue-Based Products. Caution: Not intended for direct administration into humans or animals. © 2022, 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. DeltaV is a trademark of Emerson Electric Co. COL35618 0223

gíbco