



# CTS Cell Therapy Systems

Products to help you move your research from the bench to the clinic

# Contents

Introduction to Cell Therapy Systems (CTS)	3
--	---

---

CTS products for stem cells	4
-----------------------------	---

---

CTS products for immunotherapy	6
--------------------------------	---

---

CTS reagents	8
--------------	---

---

Gibco custom media and services	10
---------------------------------	----

---

Cell therapy support resources	10
--------------------------------	----

---

Ordering information	11
----------------------	----

---

# Cell Therapy Systems (CTS)

As you move your translational stem cell, tissue engineering, and immunotherapy research toward the clinic, high-quality products and proper documentation are essential to getting it right the first time. We offer a broad array of high-quality Gibco™ Cell Therapy Systems (CTS™) products designed for use in cell therapy research applications, including media, reagents, growth factors, enzymes, selection beads, and devices, which are manufactured at FDA registered sites, certified to ISO 13485 and ISO 9001.

When you choose CTS products, you can expect:



## **cGMP-compliant documentation**

- Traceability documentation including Certificates of Analysis, Certificates of Origin, and Drug Master Files
- Helps reduce time in preparing investigational new drug (IND) submission
- All products are ready to be used as part of your IND (CMC-ready)
- CTS product labeling and intended use statements



## **Seamless transition from research to clinic**

- Defined formulations minimize lot-to-lot variability
- Manufactured under scalable cGMP conditions
- Complementary RUO products
- Extensive QA testing for sterility, endotoxin, adventitious agent, and mycoplasma on most products



## **Expert consultation**

- Regional technical support for all CTS products
- Experienced global professionals to help navigate regulatory processes from research to commercial phase
- Cell therapy expertise to help answer all of your questions
- Backed by more than 50 years of Gibco™ media experience

For more information about CTS products, go to [thermofisher.com/cts](https://thermofisher.com/cts)

# CTS products for stem cells

Regardless of the type and source of your stem cells, CTS products help you isolate, expand, differentiate, and characterize your stem cells. Enter the clinic knowing that your tailored solutions can assist with meeting your regulatory and quality requirements throughout your manufacturing process.

All CTS stem cell products are manufactured at a site that is FDA registered and has an ISO 13485–certified quality management system. The methods and controls used for the manufacturing are in conformity with current Good Manufacturing Practices (cGMP) for medical devices, 21 CFR Part 820, of the regulation.

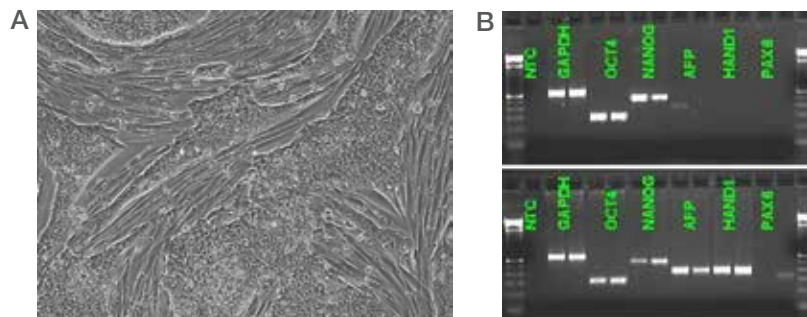
## Pluripotent stem cell products

### CTS KnockOut SR XenoFree Medium

Gibco™ CTS™ KnockOut™ SR XenoFree Medium, when formulated as a complete medium, enables the growth and expansion of human embryonic stem cells (hESCs) and human induced pluripotent stem cells (hiPSCs) in a cell culture medium containing only human-derived or human recombinant proteins. It can also be used for hESC/hiPSC cryopreservation, derivation, and differentiation studies. A Drug Master File is filed with the FDA.



For Human *Ex Vivo* Tissue and Cell Culture Processing Applications. CAUTION: When used as a medical device, Federal Law restricts this device to sale by or on the order of a physician.



**Figure 1. Xeno-free growth and gene expression of hESCs.** (A) Xeno-free growth of hESCs on feeder cells. BG01v morphology when cultured in CTS KnockOut SR XenoFree Medium on human foreskin fibroblasts (HFF) attached with Gibco™ CTS™ CELLstart™ Substrate, passage 4. (B) Maintenance of pluripotency using CTS KnockOut SR XenoFree Medium. Following 10 passages in either Gibco™ KnockOut™ Serum Replacement–supplemented medium (left lane) or CTS KnockOut SR XenoFree Medium (right lane) on HFF attached with CTS CELLstart Substrate, BG01v gene expression was examined (top). Gene expression of embryoid bodies generated from the same passage 10 BG01v/HFF cultures (bottom).

For more information about CTS products for stem cell research, go to [thermofisher.com/ctsstemcells](https://thermofisher.com/ctsstemcells)

## Neural stem cell products

### CTS B-27 Supplement, XenoFree

Formulated with only recombinant or humanized components, CTS™ B-27™ Supplement can be used to support induction of human neural stem cells (hNSCs) from pluripotent stem cells (PSCs), expansion and differentiation of hNSCs, and maintenance of mature differentiated neurons in culture. Complementary CTS™ neural reagents with CTS B-27 Supplement, XenoFree, can be found online. A Drug Master File is filed with the FDA.

For Research Use or Manufacturing of Cell-, Gene-, or Tissue-Based Products. CAUTION: Not intended for direct administration into humans or animals.



## Mesenchymal stem cell products

### CTS StemPro MSC SFM

CTS™ StemPro™ MSC SFM is a serum-free medium (SFM) specially formulated for the expansion of human mesenchymal stem cells (MSCs) and for enabling superior human MSC growth and increased consistency compared to classical serum-supplemented medium (DMEM + 10% FBS) while still maintaining their trilineage mesoderm differentiation potential (i.e., the ability to differentiate into osteogenic, chondrogenic, and adipogenic lineages). CTS StemPro MSC SFM facilitates expansion of MSCs directly from primary human bone marrow. A Drug Master File is filed with the FDA.

For Human *Ex Vivo* Tissue and Cell Culture Processing Applications. CAUTION: When used as a medical device, Federal Law restricts this device to sale by or on the order of a physician.



## Stem cell substrates

### CTS CELLstart Substrate

CTS™ CELLstart™ Substrate contains only components of human origin (xeno-free) and supports attachment of human embryonic and induced pluripotent stem cells, expansion of undifferentiated colonies, maintenance of pluripotency, and differentiation capability in serum-free medium without the need for feeder cells. CTS CELLstart Substrate can also be used with mesenchymal and neural stem cells, and for the attachment of human feeder cells (e.g., foreskin fibroblasts). A Drug Master File is filed with the FDA.

For Research Use or Noncommercial Manufacturing of Cell-based Products for Clinical Research. Research Use Only. Not for use in diagnostic procedures.



# CTS products for immunotherapy

Whether you're developing cell-based vaccines, genetically modified T cells, or other immunity-based cell therapy strategies, Gibco™ CTS™ tools and reagents support all aspects of your work—from bench to clinic and beyond into commercial applications. The CTS products provide specialized products to isolate, activate, and expand T cells, dendritic cells, and other cell types. These products are designed to facilitate the development of immunity-based cell therapy strategies and to ease your transition into the clinic.

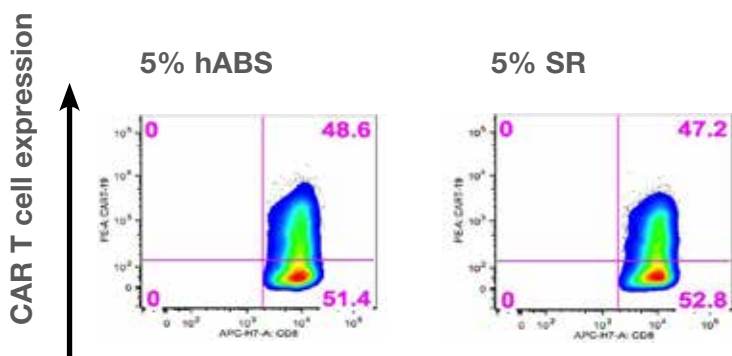
All CTS immunotherapy products are manufactured at a site that is FDA registered and has an ISO 13485–certified quality management system. The methods and controls used for the manufacturing is in conformity with cGMP for medical devices, 21 CFR Part 820, of the regulation.



## CTS Immune Cell Serum Replacement

Gibco™ CTS™ Immune Cell Serum Replacement (SR) is designed to support expansion of *in vitro* cultured human T cells when supplemented to a basal cell culture medium such as Gibco™ CTS™ OpTImizer™ T Cell Expansion SFM or Gibco™ CTS™ AIM V™ Medium. CTS Immune Cell SR is a defined xeno-free formulation and does not contain bovine or other nonhuman, animal-derived components. The CTS Immune Cell SR is available in a 50 mL bottle for small volume users, as well as a 500 mL bottle for larger volume users. For added convenience, the product can also be freeze/thawed once if smaller aliquots are needed. CTS Immune Cell SR can be supplemented to your standard base medium at similar concentrations as human serum. A Drug Master File is filed with the FDA.

This Product is For *In Vitro* Diagnostic Use.



**Figure 2. Equivalent transduction efficiency with immune cell serum replacement.** CAR transduction efficiency of expanded T cells was determined by staining with goat anti-mouse IgG (H+L).

### CTS AIM V Medium

CTS AIM V™ Medium (Therapeutic Grade) is the first commercially available defined, serum-free formulation for proliferation and manipulation of T cells and dendritic cells, and is manufactured in compliance with cGMP. CTS AIM V Medium is an FDA-cleared Class II Medical Device. A Drug Master File is filed with the FDA.

For Human *Ex Vivo* Tissue and Cell Culture Processing Applications. CAUTION: When used as a medical device, Federal Law restricts this device to sale by or on the order of a physician.

### CTS OpTmizer T Cell Expansion SFM

CTS OpTmizer T Cell Expansion SFM has been developed for the growth and expansion of human T lymphocytes. CTS OpTmizer T Cell Expansion SFM is a complete serum-free, xeno-free medium consisting of Gibco™ OpTmizer™ T Cell Expansion Basal Medium and the Gibco™ OpTmizer™ T Cell Expansion Supplement. CTS OpTmizer T Cell Expansion SFM is a Class II Medical Device. A Drug Master File is filed with the FDA.

For Human *Ex Vivo* Tissue and Cell Culture Processing Applications. CAUTION: When used as a medical device, Federal Law restricts this device to sale by or on the order of a physician.



## Culture reagents

### CTS Dynabeads CD3/CD28

Gibco™ CTS™ Dynabeads™ CD3/CD28 magnetic beads are intended for *ex vivo* isolation, activation, and expansion of human T cells in translational research. The combination of anti-CD3 and anti-CD28 antibodies on these Gibco™ Dynabeads™ magnetic beads provides both the primary and co-stimulatory signals that are required for activation and expansion of T cells. CTS Dynabeads CD3/CD28 beads are manufactured and controlled according to ISO 9001:2008 and ISO 13485:2012 requirements. A Drug Master File is filed with the FDA. In the US, CTS Dynabeads CD3/CD28 beads are available for clinical use only under an approved IND application.

For Research Use or Noncommercial Manufacturing of Cell-based Products for Clinical Research. CAUTION: Not intended for direct administration into humans or animals.

### CTS DynaMag Magnet

The Gibco™ CTS™ DynaMag™ Magnet is suitable for use with commercially available sterile blood/culture bags, tubing, and connectors. The CTS DynaMag Magnet is intended for use with CTS Dynabeads CD3/CD28 beads in clinical research.

For Research Use or Manufacturing of Cell-, Gene-, or Tissue-Based Products. CAUTION: Not intended for direct administration into humans or animals.

For more information about CTS products for immunotherapy, go to [thermofisher.com/ctsimmunotherapy](https://www.thermofisher.com/ctsimmunotherapy)



# CTS reagents

Many of our standard and specialty reagents are available as CTS products, helping to enable researchers to make a seamless transition from the bench to the clinic without having to qualify new reagents, and offering harmonized documentation for traceability.

All CTS reagents are manufactured at a site that is FDA registered and has an ISO 13485–certified quality management system. The methods and controls used for the manufacturing is in conformity with cGMP for medical devices, 21 CFR Part 820, of the regulation.

## CTS GlutaMAX-I Supplement

Gibco™ CTS™ GlutaMAX™-I Supplement, L-alanyl-L-glutamine, is a dipeptide substitute for L-glutamine and can be used as a direct substitute for L-glutamine at equimolar concentrations in mammalian and stem cell culture with minimal or no adaptation. CTS GlutaMAX-I Supplement offers great stability at both ambient temperature and during cell culture compared to glutamine. The supplement is animal origin–free and cGMP manufactured to help ensure traceability. CTS GlutaMAX-I Supplement enables you to reduce your burden in qualifying reagents during your transition from research to clinical applications. A Drug Master File is filed with the FDA.

For Research Use or For Use in Manufacturing Cell-, Gene-, or Tissue-based Products. CAUTION: Not intended for direct administration into humans or animals.



## CTS Synth-a-Freeze Medium

Gibco™ CTS™ Synth-a-Freeze™ Medium is a convenient, ready-to-use, chemically defined, protein-free liquid cryopreservation medium intended for freezing and storing a variety of mammalian cell types, including stem cells. CTS Synth-a-Freeze Medium is optimally formulated without antibiotics, antimycotics, hormones, growth factors, serum, or protein, and buffered with HEPES and sodium bicarbonate. A Drug Master File is filed with the FDA.

### Compatible human cell types include:

- Corneal epithelial cells
- Neonatal and adult dermal fibroblasts
- Neonatal and adult epidermal keratinocytes
- Aortic, pulmonary artery, and umbilical vein endothelial cells
- Neonatal and adult melanocytes
- Skeletal muscle cells
- Aortic, coronary, and pulmonary smooth muscle cells
- Neonatal and adult microvascular endothelial cells
- Neural stem cells
- Embryonic stem cells
- Mesenchymal stem cells

For Research Use or Manufacturing of Cell-, Gene-, or Tissue-based Products. CAUTION: Not intended for direct administration into humans or animals.

For more information about CTS reagents, go to [thermofisher.com/ctsreagents](https://www.thermofisher.com/ctsreagents)



### CTS TrypLE Select Enzyme

Gibco™ CTS™ TrypLE™ Select Enzyme, a nonanimal alternative for porcine trypsin, is a recombinant enzyme derived from microbial fermentation. This material is used for the dissociation of attachment-dependent cell lines from plasticware. CTS TrypLE Select Enzyme has demonstrated the ability to dissociate cells cultured both in serum-free and serum-supplemented systems. The product is provided as a 1X stock solution, formulated in DPBS with 1 mM EDTA. A Drug Master File is filed with the FDA.



For Research Use or Manufacturing of Cell-, Gene-, or Tissue-based Products. CAUTION: Not intended for direct administration into humans or animals.

### CTS DPBS

Gibco™ CTS™ DPBS is the classical Dulbecco's Phosphate-Buffered Saline (DPBS) that contains calcium and magnesium but no phenol red. CTS DPBS is manufactured in state-of-the-art cGMP- and ISO-certified facilities to help ensure the highest quality and consistency for reproducible results. Lots are tested for osmolality, pH, stability, the absence of bacterial and fungal contamination, and endotoxin.



For Research Use or Manufacturing of Cell-, Gene-, or Tissue-based Products. CAUTION: Not intended for direct administration into humans or animals.

## CTS cytokines and growth factors

With highly active, highly pure Gibco™ CTS™ cytokines and growth factors, you can expand and differentiate cell populations with more confidence in your results. We offer high-quality growth factors and cytokines for T cell, stem cell and dendritic cell applications.

CTS cytokines and growth factors are manufactured in compliance with 21 CFR Part 820, the quality system regulations for medical devices. Additionally, growth factors are manufactured under ISO 13485:2003, Medical devices—Quality management systems—Requirements for regulatory purposes. A Drug Master File is filed with the FDA.



For Research Use or Manufacturing of Cell-, Gene-, or Tissue-based Products. CAUTION: Not intended for direct administration into humans or animals.

For more information about CTS cytokines and growth factors, go to [thermofisher.com/ctsgrowthfactors](https://www.thermofisher.com/ctsgrowthfactors)

# Gibco custom media and services

We know that not all cell culture requirements are alike. We are committed to providing you with Gibco products customized to your needs—quality media you know and trust, personalized to your specifications. Many of our liquid media can be manufactured as cGMP custom CTS products, following feasibility and regulatory review to ensure they meet CTS requirements.

If you're interested in a custom CTS product, please send an inquiry to [custommedia@lifetech.com](mailto:custommedia@lifetech.com)

## Large-scale cGMP custom media

For large-scale clinical or commercial biomanufacturing applications, rely on our validated cGMP custom services.

- Liquid in batches from 10 to 10,000 L
- Dry powder media (DPM) in batches from 1 to 8,000 kg
- Advanced Granulation Technology™ (AGT™) media in batches from 50 to 6,000 kg

## Custom packaging options

Choose to receive your Gibco™ custom media in the packaging that best suits your needs. We have many different options for liquid and powder media in a variety of package sizes—available in both bottles and bags—to manage small-, intermediate-, and large-scale needs.

## cGMP manufacturing sites

We maintain two primary Gibco™ cell culture manufacturing locations—in the US and Scotland—and three primary

Gibco™ serum and/or protein product manufacturing locations—in the US, New Zealand, and Australia. For reliable global service and contingency planning, we welcome visits and audits of our cGMP facilities to help facilitate regulatory approvals of your products and services.

## Process development custom services

Choose the Gibco™ Custom Services team to help reduce process development inefficiencies, and improve time and cost performance using our latest technologies.

## MediaExpress and Rapid Research

Gibco™ MediaExpress™ and Rapid Research services are specifically designed for small-scale, non-cGMP custom orders when speed matters most. We offer Gibco product quality in small batches for quick turnaround and smooth transition to cGMP scale-up.

# Cell therapy support resources

Get the cell therapy support you need—the way you want it. Cell therapy research can be challenging and time-consuming: finding support shouldn't be. That's why we give you easy access to the resources and support you need to be successful in moving your research from the bench to the clinic.

Find the support you need at [thermofisher.com/celltherapysupport](https://thermofisher.com/celltherapysupport)

## Ordering information

Product	Quantity	Cat. No.
CTS immunotherapy products		
CTS™ Immune Cell Serum Replacement*	50 mL	A2596101
CTS™ Immune Cell Serum Replacement*	500 mL	A2596102
CTS™ AIM V™ Medium**	1 L	0870112DK
CTS™ AIM V™ Medium**	10 L	0870112BK
CTS™ Dynabeads™ CD3/CD28†	10 mL	40203D
CTS™ DynaMag™ Magnet‡	1 each	12102
CTS™ OpTmizer™ T Cell Expansion SFM** (bottle)	1 L	A1048501
CTS™ OpTmizer™ T Cell Expansion SFM** (bag)	1 L	A1048503
CTS™ GM-CSF Recombinant Human Protein†	100 µg	CTP2011
CTS™ GM-CSF Recombinant Human Protein†	1 mg	CTP2013
CTS™ TNF-α Recombinant Human Protein†	100 µg	CTP3011
CTS™ TNF-α Recombinant Human Protein†	1 mg	CTP3013
CTS™ Interleukin 2 Recombinant Human Protein†	100 µg	CTP0021
CTS™ Interleukin 2 Recombinant Human Protein†	1 mg	CTP0023
CTS™ Interleukin 4 Recombinant Human Protein†	100 µg	CTP0041
CTS™ Interleukin 4 Recombinant Human Protein†	1 mg	CTP0043
CTS™ Interleukin 7 Recombinant Human Protein†	100 µg	CTP0071
CTS™ Interleukin 7 Recombinant Human Protein†	1 mg	CTP0073
CTS™ DPBS (with calcium chloride and magnesium chloride)‡	1 L	A1285801
CTS™ DPBS (without calcium chloride and magnesium chloride)‡	1 L	A1285601
CTS™ CELLstart™ Substrate†	2 mL	A1014201
CTS™ GlutaMAX™-I Supplement†	100 mL	A1286001
CTS™ KnockOut™ SR XenoFree Medium**	100 mL	12618012
CTS™ KnockOut™ SR XenoFree Medium**	500 mL	12618013

Product	Quantity	Cat. No.
CTS immunotherapy products		
CTS™ KnockOut™ SR XenoFree Kit**	100 mL	A1099201
CTS™ KnockOut™ SR XenoFree Kit**	500 mL	A1099202
CTS™ KnockOut™ DMEM†	500 mL	A1286101
CTS™ TrypLE™ Select Enzyme‡	100 mL	A1285901
CTS™ FGF-Basic Full Length Recombinant Human Protein†	100 µg	CTP0261
CTS™ FGF-Basic Full Length Recombinant Human Protein†	1 mg	CTP0263
CTS™ Interleukin 6 Recombinant Human Protein†	1 mg	CTP0063
CTS™ Interleukin 6 Recombinant Human Protein†	100 µg	CTP0061
CTS™ Stem Cell Factor (SCF) Recombinant Human Protein†	100 µg	CTP2111
CTS™ Stem Cell Factor (SCF) Recombinant Human Protein†	1 mg	CTP2113
CTS™ TGF-β 1 Recombinant Human Protein†	100 µg	CTP9211
CTS™ TGF-β 1 Recombinant Human Protein†	1 mg	CTP9213
CTS™ FLT3 Ligand Recombinant Human Protein†	100 µg	CTP9411
CTS™ FLT3 Ligand Recombinant Human Protein†	1 mg	CTP9413
CTS™ B-27™ Supplement, XenoFree‡	10 mL	A1486701
CTS™ Neurobasal™ Medium (1X)†	500 mL	A1371201
CTS™ Neurobasal™-A Medium (1X)†	500 mL	A1371001
CTS™ Synth-a-Freeze™ Medium†	50 mL	A1371301
CTS™ Hibernate™-A Medium†	500 mL	A1370501
CTS™ Hibernate™-E Medium†	500 mL	A1370601
CTS™ N-2 Supplement (100X)†	5 mL	A1370701
CTS™ KnockOut™ DMEM/F-12†	500 mL	A1370801
CTS™ StemPro™ MSC SFM**	500 mL	A1033201

**CAUTION:** Not Intended for Direct Administration into Humans or Animals, unless noted otherwise.

\* For *In Vitro* Diagnostic Use.

\*\* For Human *Ex Vivo* Tissue and Cell Culture Processing Applications.

† For Research Use or Noncommercial Manufacturing of Cell-based Products for Clinical Research.

‡ For Research Use Only or Manufacturing of Cell-, Gene-, or Tissue-based Products.

Find out more at [thermofisher.com/cts](https://thermofisher.com/cts)

**gibco**

Find out more at [thermofisher.com/cts](https://thermofisher.com/cts)

**ThermoFisher**  
S C I E N T I F I C

**For Research Use Only. Not for use in diagnostic procedures.** © 2016 Thermo Fisher Scientific Inc. All rights reserved.  
All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. B-27 is a trademark  
of the Board of Trustees of Southern Illinois University **COL11528 0516**