



# Enabling your pluripotent stem cell therapy research

Translate your research to the clinic with Cell Therapy Systems products

Advancing your induced pluripotent stem cell (iPSC) therapy research to clinical applications requires careful material selection because the quality of starting materials can significantly impact the properties of your final stem cell therapy product. Gibco™ Cell Therapy Systems (CTS™) products have been

developed to ease the transition from stem cell therapy research to clinical applications by providing high-quality, GMP-manufactured, commercial-scale ancillary materials with a high degree of qualification, traceability, and regulatory documentation.

When you choose CTS products, you can expect:



### cGMP-compliant manufacturing

- Manufactured in conformity with GMP and follow USP 1043\* and Ph Eur 5.2.12 regulations
- Internal manufacturing sites are US Food and Drug Administration (FDA)-registered, ISO 13485-certified, and regularly audited



### Testing and documentation

- Traceability documentation, including Drug Master Files and/or Regulatory Support Files, and Certificates of Origin
- Product safety testing—including sterility, endotoxin levels, and mycoplasmas on applicable products



### Proven use

- Used in FDA-approved and EMA-approved CAR T therapies [1,2] and the first FDA-approved therapeutic cancer vaccine [3]
- Used in over 100 clinical trials

\* CTS products are manufactured to meet the ancillary material responsibilities for cell-, gene-, and tissue-engineered products. Other aspects of USP 1043 are the responsibility of the end user to assess. Thermo Fisher Scientific cannot fulfill USP 1043 in regard to application and therapy-specific aspects (e.g., use in a finished therapeutic, assessment of removal from a finished therapeutic, and possibly biocompatibility, cytotoxicity, or adventitious agent testing).



We support the development of your iPSC therapy from the earliest stages of research all the way to the clinic. We offer high-quality Research Use Only products to support your early cell therapy development and CTS products as you move toward clinical and commercial applications. Most Gibco™ media and supplements are manufactured under GMP conditions at sites that use methods and controls

that conform to current Good Manufacturing Practices (cGMP) for medical devices. These manufacturing sites are ISO 13485– and ISO 9001–certified, and the rigorous practices we adhere to at these sites help ensure the consistency, reliability, and high quality of a wide variety of media and reagents for iPSC therapy workflows.



### Reprogramming

Invitrogen™ CTS™ CytoTune™-iPS 2.1 Sendai Reprogramming Kit



### Banking and recovery

Gibco™ CTS™ PSC Cryopreservation Kit  
Gibco™ CTS™ PSC Cryomedium  
Gibco™ CTS™ RevitaCell™ Supplement



### Expansion and gene editing

**Expansion media systems**  
Gibco™ CTS™ Essential 8™ Medium  
Gibco™ CTS™ Vitronectin (VTN-N)  
Invitrogen™ Recombinant Human Protein  
Gibco™ rhLaminin-521  
Gibco™ CTS™ Versene™ Solution  
Gibco™ CTS™ TrypLE™ Select Enzyme  
CTS RevitaCell Supplement

**Genome editing**  
Gibco™ TrueCut™ Cas9 Protein (CTS™-Prototype)  
Invitrogen™ TrueGuide™ Synthetic gRNAs  
Invitrogen™ Neon™ Transfection System



### Differentiation

Gibco™ CTS™ Essential 6™ Medium  
CTS™ KnockOut™ SR XenoFree Medium  
Gibco™ CTS™ N-2 Supplement  
Gibco™ B-27™ Supplement, XenoFree  
Gibco™ CultureOne™ Supplement

## Characterization

Applied Biosystems™ TaqMan® hPSC Scorecard Panel—for assessing trilineage differentiation potential  
Applied Biosystems™ PrimeView™ gene expression assays (compatible with the PluriTest™ assay)—for testing pluripotency  
Applied Biosystems™ KaryoStat™ Assays—for checking genomic stability  
Invitrogen™ CellModel™ Services—for stem cell characterization

## Ordering information

Product	Cat. No.
B-27 Supplement (50X), serum free	17504044
CTS CytoTune-iPS 2.1 Sendai Reprogramming Kit	A34546
CTS Essential 6 Medium	A4238501
CTS Essential 8 Medium	A2656101
CTS KnockOut SR XenoFree Medium	12618012
CTS N-2 Supplement	A1370701
CTS PSC Cryomedium	A4238801
CTS PSC Cryopreservation Kit	A4239301
CTS RevitaCell Supplement (100X)	A4238401

Product	Cat. No.
CTS TrypLE Select Enzyme	A1285901
CTS Versene Solution	A4239101
CTS Vitronectin (VTN-N) Recombinant Human Protein, Truncated	A27940
CultureOne Supplement (100X)	A3320201
Neon Transfection System	MPK5000
rhLaminin-521	A29248
TrueCut Cas9 Protein (CTS-Prototype)	A45220P

## References

- Lu TL, Pugach O, Somerville R (2016) A rapid cell expansion process for production of engineered autologous CAR-T cell therapies. *Hum Gene Ther Methods* 27:209–218.
- <http://thermofisher.mediaroom.com/2017-08-30-First-FDA-Approved-Cell-Therapy-for-Leukemia-Utilizes-Thermo-Fisher-Scientifics-CTS-Dynabeads-Technology>
- Madan RA, Gulley JL (2011) Sipuleucel-T: harbinger of a new age of therapeutics for prostate cancer. *Expert Rev Vaccines* 2:141–150.

Find out more at [thermofisher.com/stemcelltherapy](http://thermofisher.com/stemcelltherapy)



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