



Certificate of Analysis

CTS(TM) Immune Cell SR

Catalog Number: A25961

Lot Number: 2008883

Storage Temperature: -5 to -20C

Storage Instructions: Protect from light

Expiration Date: 2020-02

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

TEST	SPECIFICATION	RESULT	UNITS
¹ Endotoxin Testing (LAL Method)	<0.0 to <10.0	<0.900	EU/mL
² HCV Antibody Screening	Non Reactive	Non Reactive	
³ Hepatitis B Surface Antigen Screening	Non Reactive	Non Reactive	
⁴ HIV 1 & 2 Antibody Screening	Non Reactive	Non Reactive	
⁵ Mycoplasma qPCR Detection Assay	Negative	Negative	
⁶ Osmolality	>=440 to <=515	472	mOsm/kg
⁷ pH	>=6.9 to <=7.7	7.4	
⁸ Sterility Testing	Negative	Negative	
⁹ T Cell Functional Assay	Acceptable	Acceptable	
T Cell Functional Assay: Test % Viability	Acceptable	Acceptable	



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(Continued)

Read SDS.

CAUTION: Human origin materials are non-reactive (donor level) for Anti-HIV 1 and 2, Anti-HCV, and HBsAg. Handle in accordance with established bio-safety practices.

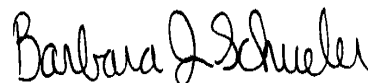
Formulated with human or recombinant proteins.

Do not Heat-Inactivate.

The manufacturing facility is in compliance with 21 CFR Part 820 Quality System Regulation and is certified to ISO 13485.

GIBCO brand, Thermo Fisher Scientific cell culture liquid products are prepared by an aseptic process for which each step has been validated to ensure that all products meet the industry standard sterility assurance level of 10^{-3} ; i.e. product that demonstrates a contamination level of no more than 1 of 1,000 units during the manufacturing process. The highest level of sterility assurance (equal to or greater than 10^{-6}) cannot be achieved without terminal sterilization which is harmful to the performance of cell culture products.

For support related to CTS (TM) products, please visit us at: www.lifetechnologies.com/celltherapyresearchsupport, technical support team at: techsupport@lifetech.com or contact us by phone at: 1-800-755-6288 extension 40562.



Quality Systems Department

Date: 23-Aug-2018

REFERENCES:

- 1 Current United States Pharmacopeia, <8> Bacterial Endotoxins Test.
- 2 FDA Licensed / Approved blood screening tests.
- 3 FDA Licensed / Approved blood screening tests.
- 4 FDA Licensed / Approved blood screening tests.
- 5 Thermo Fisher Scientific Specifications. The Mycoplasma qPCR Detection Assay uses Power SYBR® Green detection technology and a Real-Time Polymerase Chain Reaction to amplify a target DNA sequence common to a wide variety of mycoplasmas.
- 6 Thermo Fisher Scientific Specifications.
- 7 USP/EP
- 8 Current edition of USP.
- 9 Each lot of CTS Immune Cell SR is tested for its ability to expand primary human T cells when supplemented to a final concentration of 2% to CTS OpTmizer T cell Expansion SFM. Cryopreserved cells from a qualified cell donor are recovered, and primary human T cells are isolated and activated using Dynabeads CD3/CD28 CTS. The activated cells are cultured with Dynabeads in CTS Immune Cell SR-supplemented medium for 4 days. The expanded cells are determined acceptable by evaluation of number of viable cells according to internal specifications.