

CERTIFICATE OF ANALYSIS – FROZEN CD4+/CD8+ CELLS IN VIALS

Global Donor
Registration ID:
Collection Date/Time:

Batch Number:

For Research Use Only

Manufacturing Facilities

Unless otherwise noted, allogeneic starting material is sourced from donors in the Gift of Life Marrow Registry, collected at the Adelson Gift of Life – NMDP Collection Center and tested, processed and cryopreserved at the Gift of Life Center for Cell and Gene Therapy, all located at 5901 Broken Sound Pkwy NW, Boca Raton, Florida 33487. Accreditations, certifications and licenses can be found at <https://www.giftoflifebio.com/about/standards>.

Product Type and Collection Information ¹

Product Type	Collection Date / End Time	Anticoagulant
CD4+/CD8+ cells in vials, unstimulated, frozen, 1 mL, XX x10 ⁶ FOR RESEARCH USE ONLY		ACD-A

¹ Unless otherwise noted, all products are collected by apheresis using the Terumo Optia CMNC protocol.

Product Flow Cytometry

	Post-Collection, Pre-Processing Results	Post-Processing, Pre-Freeze ² Results
Viability %		
Total Viable Leukocytes		

² Post-processing, pre-freeze testing is done before the addition of cryoprotectant and media.

Product Processing and Cryopreservation Information

Processing Method	Processing Date / End Time	Software (if automated)
✓ Manual or Automated		

Cryopreservation	Cryo Date / End Time	Cryoprotectant
Mechanical freezing at -80°C		DMSO 10% - CryoStor
Stored in LN2 vapor		DMSO 10% - CryoStor

CERTIFICATE OF ANALYSIS

Batch Number:

Donor Information³

Age	Sex (Assigned at birth)	Ethnicity	Weight	Height	Tobacco Use	Blood Type

³ Note that some donor information is self-reported and privacy laws prohibit Gift of Life from independently verifying the accuracy of this information.

Donor HLA Typing⁴

HLA-A	HLA-B	HLA-C	HLA-DRB1

⁴ Date above is testing date.

Donor Infectious Disease Markers⁵

HIV I/II ABY	HIV/NAT	HCV ABY	HCV NAT	HBsAG	HBV NAT
Negative	Non-Reactive	Negative	Non-Reactive	Negative	Non-Reactive

HBCore ABY	WNV NAT	Chagas ABY	Syphilis	HTLV I/II ABY	CMV
Negative	Non-Reactive	Negative	Non-Reactive	Negative	Non-Reactive

⁵ Date for each test above is the date specimen collected.

Infectious disease testing was performed by ViroMed Laboratories (CLIA # 24D0400424), a subsidiary of LabCorp. ViroMed is contracted by Gift of Life and meets all vendor qualification requirements. A negative result indicates that a test was found to be negative within 7 days of collection for MNC-A products and 30 days for HPC-A products.

QA Completed By	Date	QA Approved By	Date

Refer to the Gift of Life Biologics website (www.giftoflifebio.com) for terms and conditions, thawing protocol and questions and answers. Gift of Life Biologics cannot guarantee the biological function, or any other properties associated with cell performance in a researcher’s assay or culture systems. Gift of Life Biologics assures the cells will meet specifications only when assessed, before washing, by our test methods.

THE CELLS ARE INTENDED FOR **IN VITRO RESEARCH USE ONLY** AND ARE NOT APPROVED FOR DIAGNOSTIC, THERAPEUTIC, OR CLINICAL APPLICATIONS. THE CELLS ARE NOT APPROVED FOR HUMAN OR VETERINARY USE IN VIVO.