

 Indiana University Health	Original Creation Date: Not Set	Publication Date: Not Set
	Owner: Dave Schwering (Manager-Quality)	Next Review: Not Set
	Category: Labs AHC	
	Education: Level 4	

Approval Signatures: Dave Schwering (Manager-Lab)

Procedure Packaging and Shipment of MNC Product to Manufacturing Facility for Preparation of CD4CAR Cells for Protocol #CTO-IUSCCC-ICG122-101

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

I. PURPOSE

This SOP details the steps for packaging and shipment of the autologous Apheresis MNC product to a manufacturing facility for preparation of CD4CAR cells.

II. SCOPE

This procedure applies to the packaging and shipment of autologous Apheresis MNC for patients enrolled on IRB Protocol # CTO-IUSCCC-ICG122-101. All Cellular Therapy Laboratory Technologists will follow this procedure

III. STATEMENTS/REQUIREMENTS

Any exceptions to this policy must be approved by the CTL Processing Facility Medical Director. Any exceptions that deviate from the study protocol must be approved by the Study PI.

- This procedure is used to support Protocol #CTO-IUSCCC-ICG122-101, A Phase I, Multicenter Study of CD4-directed chimeric antigen receptor engineered T-cells (CD4CAR) in patients with Relapsed or Refractory CD4 Positive Lymphoid Hematological Malignancies.
- Cryopreservation of the leukapheresis material must occur within 24 hours of the end of apheresis collection.
 - Leukapheresis material can be stored at room temperature for a maximum of 1 hour following the end of apheresis collection.
- All study forms are found in the corresponding confidential study binder.
- Always contact study site manager for any questions or concerns.
- Any deviation that has the potential to impact the quality, purity, safety or testing of the MNC product must be reported to the study site manager.
 - Deviations must be reported within 24 hours of discovery.

IV. DEFINITIONS

AABB: Association for the Advancement of Blood and Biotherapies

AWB: Air Waybill

CTL: Cellular Therapy Laboratory

CTI: Indiana University Simon Comprehensive Cancer Center (Coordinating Center)

Louisville Manufacturer: University of Louisville Brown Cancer Center

FACT: Foundation for the Accreditation of Cellular Therapy

FDA: Food and Drug Administration

HPC(A): Hematopoietic Progenitor Cells by Apheresis

ISBT: International information standard for coding and labeling of cell therapy products

MNC: Mononuclear Cells PI: Principal Investigator RC: Research Coordinator

SOP: Standard Operating Procedure

V. EQUIPMENT/RESOURCES

Autologous MNC Product

VeriCor Transport Cooler Shipping Container

Shipping Address Label

Bubble Wrap

Temperature Monitoring Device

Biohazard Bag

Absorbent Pads

'Do Not X-Ray' labels

Courier Shipping Documentation

VI. PROCEDURE

- A. Apheresis Notification of MNC, Apheresis Product Pick-up
 - i. Apheresis RN will notify CTL that the product is ready for pick-up.
 - ii. The product will be immediately picked up by CTL.
- B. Maintaining Chain of Custody from Apheresis RN to CTL Technologist
- C. After the Apheresis RN completes the collection procedure, the RN will complete Appendix 10.4 Apheresis Tracking Log.
 - i. "Gram staining result on apheresis product: _____" will be left blank by Apheresis and Cellular Therapy if it is a fresh shipment.
 1. This gram stain will be completed by the facility manufacturing the IP.
 - ii. Keep a copy of Appendix 10.4 Apheresis Tracking Log in the CTL chart.
- D. The Apheresis RN releasing the product must also sign and record time of release on the Autologous Product Description & Quality Certificate form F-561a.
 - i. The CTL Technologist will then sign the form to document taking custody of the product.
- E. Apheresis product will be received by the Cellular Therapy lab and then transferred to the Cellular Immunotherapy and Transduction lab for manufacturing (or shipping if Louisville will be manufacturing) within one hour of collection end time.
 - i. If more time is required, please place into appropriate temperature monitored storage (2-8 °C) until the time of transfer occurs.
 - ii. Provide temperature graph of the refrigerator used to store the product to CTL QA.

- F. The product will be transported at room temperature to the Cell Therapy Lab in the VeriCor transport cooler.
- G. Product Receipt into CTL
- H. The product will be received and logged into the F-001 CTL Activity Log according to SOP PST 005 Procedure Receipt of Cellular Therapy Products
- I. Labeling the Apheresis Material
- J. Prior to distribution the product should be labeled according to PST 008 [Procedure: Product and Reagent Labeling](#) .
 - i. Use ISBT product code S1303 MNC, Apheresis Citrate/xx/Refrigerated/For Further Processing.
 - 1. Include the study identification number next to the MRN.
 - ii. A second technologist will verify the label is correct and document on [F-406 Verification of Product Labeling: Autologous MNC](#)
 - iii. Remove the Apheresis Collection Label and place in patient chart.
 - iv. Affix final product label to bag
- K. Packaging of the Fresh Apheresis Material for Shipment
 - i. The product will be released to the CIT for manufacturing or for shipment to an outside facility for manufacturing.
 - 1. Call the **Director Cell Immunotherapy and Transduction (GMP Facility)** listed in the CTO-IUSCCC--ICG122-101 Cellular Therapy Manual to schedule the product transfer.
 - ii. The product must not remain at room temperature longer than 1 hour.
 - 1. If there is a delay, store the product at 2-8 °C in appropriate temperature monitored storage.
- L. Product Release from CTL
 - i. The product will be release to CIT personnel for manufacturing or shipment to the appropriate manufacturer.
 - 1. Apheresis product needs to arrive at manufacturing facility within 24 hours of collection.
 - 2. CIT will complete (as needed)
 - a. Appendix 10.1 CD4CAR T Cell Shipping Memo
 - b. Appendix 10.5 Cell Product Receipt Form
 - c. Appendix 10.2 CryoShipper Shipping Transport Label
 - ii. The release of the product will be documented on the F-001 CTL Activity Log according to SOP PST 006 [Procedure Cellular Therapy Product Release](#) .
 - iii. Complete Appendix 10.7 Chain of Custody Log
 - 1. Keep a copy and give the original to the CIT personnel.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

The experimental product described in this protocol will be given to subjects with unmet medical needs for which there are no effective therapies known at this time.

VIII. REFERENCES

AABB Standards for Cellular Therapy Product Services, current edition.

FDA CFR Title 21, Part 1271 Human Cells, Tissues and Cellular and Tissue Based Products
FACT Standards, current edition.

CTO-IUSCCC--ICG122-101 Cellular Therapy Manual

IX. FORMS/APPENDICES

CTO-IUSCCC--ICG122-101 Cellular Therapy Manual Forms (see secure drive protocol folder for current version)

- Appendix 10.1 CD4CAR T Cell Shipping Memo
- Appendix 10.2 CryoShipper Shipping Transport Label
- Appendix 10.4 Apheresis Tracking Log
- Appendix 10.5 Cell Product Receipt Form
- Appendix 10.6 Product Label examples
- Appendix 10.7 Chain of Custody Log
-

BMT Forms:

F-CL-2.00-1 Autologous Pre-CAR T-cell Therapy Evaluation Checklist

F-CL-20.00-2 Request for Processing Order (Autologous Product for CAR T-cell Manufacturing)

F-001" F-001 CTL Activity Log"

F-561a Autologous Product Description and Quality Certificate

X. APPROVAL BODY

See protocol.