



Indiana University Health

Cellular Therapy Laboratory

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SOP, Form, Label and Regulatory Update Review

F-028 v.04.17.2021

Document Type	Change Control #	Document #	New	Revision	Document Title
SOP					
Form					
Label					
Other	Janssen Convykti Receipt and Storage Packing and Shipping Manual				

Staff Education / Changes to Review:					Effective Date:
EDUCATION LEVEL	<input type="checkbox"/> I	<input type="checkbox"/> II	<input type="checkbox"/> III	<input type="checkbox"/> IV	version 3.0 Effective 10.03.2022
• page 2 → "citta-cel CAR-T" substituted with "D product"					

CTL Staff Review:	Initials	Review Date	Training documentation will be in MTS.

Review and Approval:			Approval Title
			CTL Operations Director
			CTL QA Supervisor
			CTL Medical Director
			Cellular Therapy Processing Facility Director (Refer to CTCQA 019)

Packing and Shipment of White Blood Cell Apheresis Collection for Central Cryopreservation Manual

Version 3

April 2022



Requirements for US Commercial CARVYTKI™

Packing and Shipment of White Blood Cell Apheresis Collection for Central Cryopreservation Manual

This manual provides requirements to support supply chain standards, within the D product commercial manufacturing process, related to packing and shipment of White Blood Cell (WBC) apheresis material for central cryopreservation. The requirements in this manual are intended to be incorporated into each site's operating procedures.

Abbreviations

CAR-T	chimeric antigen receptor-t cell
CCPC	central cell processing center
CoC	chain of custody
CoI	chain of identity
WBC	white blood cells

Definition of Terms

CoC/CoI Portal	The Chain of Custody (CoC)/ Chain of Identity (CoI) management portal used by apheresis site staff for labelling and tracking a patient's order for CARVYTKI™.
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Shipment of Fresh Apheresis Material to Central Cryopreservation Site

- Janssen will create the order with the Courier
- On the day of apheresis, you will receive a Credo Cube shipper to ship the WBC apheresis material directly to a Central Cell Processing Center (CCPC). This shipper maintains a 2 to 8-degree Celsius temperature range. The type of shipper may vary by region.



Remove the existing air waybill from the outer corrugate the shipper was delivered in.

Do not remove the Central Cryopreservation kit pouch. It will be used by the CCPC.



Pack and ship the WBC apheresis material into the Credo Cube shipper.

You will also receive:

- A site kit pouch and
- A Central Cryopreservation kit pouch inside an inner compartment.

The site kit pouch includes:

- An inactivated temperature tracking device
- A cryogenic containment pouch
- And the air waybill for shipment to the CCPC.



Contact your designated Janssen Representative if any contents are missing.



Activate the temperature tracking device, and close and secure the top panel of the shipper.



Place the foam insert on top of the inner compartment, place the remaining lid on top of the foam insert, and then secure the outer corrugate closed.



SCAN or ENTER the packing insert CoI identifier and any other requested CoC details into the CoC/CoI Portal.



Finally, place the package insert and the air waybill into the clear packing envelope on the outside of the shipper.

If your site is required to ship additional samples with the WBC apheresis material, verify that the samples match the intended patient. Place the samples into the shipper with the WBC apheresis material.

The WBC apheresis material is now ready to be picked up by the courier

A quick note on scheduling:

- Janssen and the CCPC will coordinate pick-up of the WBC apheresis material from your site on the day of the scheduled apheresis.
- Contact your designated Janssen representative immediately if the packed shipper will not be ready for pickup at the designated or standard assigned time.
- If the pickup time is delayed, alternate plans may need to be implemented based on flight or ground transportation constraints.

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For questions related to the information in this manual, contact your designated Janssen Janssen representative.