

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

Version 4

October 2023



Requirements for US Commercial CARVYKTI®

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

This manual provides requirements to support supply chain standards 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 treatment center's operating procedures.

Abbreviations

AWB	Air Waybill
CAR-T	Chimeric Antigen Receptor-T Cell
CCPC	Central Cell Processing Center
CoC	Chain of Custody
CoI	Chain of Identity
TIC	Thermal Isolation Chamber
VIP	Vacuum Insulated Panels
WBC	White Blood Cell

Definition of Terms

CoC/CoI Portal	The Chain of Custody (CoC)/Chain of Identity (CoI) management portal is used to track the handoffs throughout the CARVYKTI® order fulfillment process.
----------------	--

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.
- Verify that the Order ID/subject number on the AWB matches the Order ID/subject number listed within the CoC/CoI Portal.
- Remove the existing AWB from the clear packing envelope on top of the outer corrugate box.



Open the outer corrugate box containing the empty Credo Cube shipper.



Open the top panel and remove the VIP Panel.



Open the White TIC Panel and remove it.



Do not remove the brown payload box or Central Cryopreservation kit pouch. It will be used by the CCPC.

You will also receive:

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

The site kit pouch includes:

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



Contact your designated Janssen representative if any contents are missing.



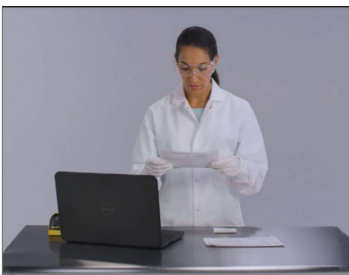
Pack and ship the WBC apheresis material into the Credo Cube shipper.



Activate the temperature tracking device, close, and secure the White TIC Panel on top of the brown payload box.



Place the VIP Panel on top of the White TIC Panel, and then secure the inner and 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 packing insert and the air waybill into the clear packing envelope on the outside of the shipper.

If your treatment center 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 pickup of the WBC apheresis material from your treatment center 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.

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

Version 4

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