



Indiana University Health

Apheresis

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### SOP, Form, Label and Regulatory Update Review

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Document Type	Change Control #	Document #	New	Revision	Document Title
SOP					
Form					
Label					
Other	<i>Janssen Carvykti Cell Collection and Management Manual</i>				

Staff Education / Changes to Review:					Effective Date:
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<i>• Add definition of DIN/SEC-DIS</i>					

Apheresis Staff Review:	Initials	Review Date

*Training documentation will be in MTS*

Review and Approval:	Approval Title
	AP/CTL Operations Director
	AP/CTL QA Specialist
	Therapeutic Apheresis Medical Director
	Pediatric Apheresis Collection Facility Medical Director

# Cell Collection and Management Manual

Version 3

April 2022



Requirements for US Commercial CARVYKTI™

# Cell Collection and Management Manual

**This manual provides apheresis collection and management details for CARVYKTI™. Follow the apheresis eligibility requirements outlined below and patient eligibility according to institutional procedures and policies.**

**The responsible person at the site should notify the appropriate Janssen representative if evidence of (1) rapid disease progression or (2) suspected central nervous system involvement is observed between scheduling cell collection and the cell collection procedure.**

**Select the cryopreservation option prior to order submission. This will then ensure the proper shipper is sent to the site. Janssen will coordinate pick-up and delivery activities for patient material designated for an off-site (central) cryopreservation laboratory. Hospital sites qualified for local cryopreservation will manage their capacity within the cell processing laboratory. Janssen will coordinate pick-up of the cryopreserved apheresis material.**

**Apheresis collection bags should have 4 to 12 inches of tubing following collection to allow for future processing by welding onto this tubing.**

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**Abbreviations**

CAR-T	chimeric antigen receptor t cell
CoC	chain of custody
CoI	chain of identity
ISBT	information standard for blood and transplant
WBC	white blood cells

**Definition of Terms**

Treatment Center Portal	A website-based order management platform to enable treatment site staff to enroll a patient, submit an order, and monitor the order journey for CARVYKTI™.
CoC/CoI Portal	The Chain of Custody (CoC)/ Chain of Identity (CoI) management portal used by the apheresis site staff for labelling and tracking a patient's order for CARVYKTI™.

## Donation Eligibility for CARVYKTI™

1. Confirm appropriate Donor Infectious Disease testing was performed as per regional requirements.
2. It is recommended patients meet the following criteria to be eligible for apheresis.
  - Hemoglobin  $\geq 8.0$  grams/dL
  - Platelets  $\geq 50 \times 10^9/L$
  - Absolute Lymphocyte Count  $\geq 0.3 \times 10^9/L$
  - Absolute Neutrophil Count  $\geq 0.75 \times 10^9/L$

## Scheduling apheresis Pick-up Date

1. Use the Treatment Center Portal to schedule a pick-up date indicating the cryopreservation option. Once scheduled, Janssen will coordinate courier logistics.

## Printing labels

1. Print the Packing Insert from the CoC/CoI Portal.
2. Print the cell collection bag labels from the hospital system following ISBT 128 (or equivalent) requirements. Perform label content verification as per site procedures.

## Cell Collection

1. The use of Anticoagulant Citrate Dextrose solution, solution-A (ACD-A) or ACD-A plus heparin is permissible. Use of heparin alone is not permitted.
2. Affix the cell collection bag labels to the cell collection bag according to site procedures. Confirm patient identity against collection bag label prior to the start of collection.
3. Perform peripheral blood cell collection according to institutional procedures and policy for peripheral blood mononuclear cell collection.
4. Target a collection of  $9.0 \pm 3.0 \times 10^9$  WBC. A minimum of  $\geq 1.0 \times 10^9$  WBC is required.
5. Place the cells at 2°C to 8°C as soon as practical within 1 hour of apheresis.
6. Enter collection details including DIN, patient weight, and collection end time into the CoC/CoI Portal.



If  $\geq 1.0 \times 10^9$  WBCs is not collected on the first apheresis attempt, communicate with Janssen Global Cell Collection.

## Cell Management and Transport

1. If using off-site central cryopreservation, transfer the apheresis material to the appropriate location as per site procedure. See the *Packing and Shipment of Mononuclear Cell Apheresis Collection for Central Cryopreservation Manual* for further details.
2. If performing local cryopreservation, transfer the apheresis material to the cell processing laboratory according to site procedures. See the *Cell Cryopreservation Procedure Manual* for further details regarding cryopreservation.
3. Manage product tracing (CoC/CoI) for the apheresis material according to site procedures.

For questions related to the information in this manual, contact Janssen Global Cell Collection.