

Cell Collection and Management Manual

Summary of Changes – updated to Version 5. January 2025

- Front page – manual Design updated to New J&J branding
- Front page – internal document number TV-TEC-309939 added
- Front page – version number and effective month/year updated
- Page 3 Abbreviations – DIN added
- Page 3 Abbreviations – IDT added
- Page 4 Donation Eligibility for CARVYKTI®
 - Step 1 changed from “per regional requirements” to “per required under all applicable law”
 - Step 2 – 8.0 grams/dL to 8.0 g/dL
- Page 5 Step 4 – added following sub-bullet points for clarity:
 - If a patient’s Pre-WBC count is performed and it is $> 12 \times 10^6$ WBC/mL, notify Janssen prior to starting the apheresis collection.
 - The minimum apheresis collection volume required is 38 mL.
 - Janssen only accepts a single collection; multiple collections cannot be combined.
 - Record the collection volume and collection end time with the local time zone
 - on the collection label.
 - WBC counts and sterility testing of the apheresis material are not required by Janssen upon completion of the apheresis procedure.
- Page 5 Step 5
 - Added “(10cm to 30cm)” SI measurement
 - Added following sub-bullet point:
 - To prevent potential leakage, remove all the accessory lines (bulbs and the filter) attached to the collection bag, and perform the heat seal technique according to your site procedure before packaging the shipment.
- Page 5 Step 6 – added following Note:
 - Please notify Janssen if any of the requirements are not met during the process
- Page 6 Step 7 – added sub-bullet point for clarity:
 - Ensure the patient’s name on the apheresis bag label is accurately reflected on the apheresis bag label and COC/COI portal, including the middle name or middle initials, if applicable.
- Page 6 Step 8 added two images to give examples of acceptable and unacceptable tubing configuration
- Page 6 Cell Management and Transport Step 1 – added “to complete packaging steps” after “location” to clarify the purpose of transferring the apheresis material.
- Right Footer (Page 2 to 6) changed from “Janssen Biotech, Inc. CONFIDENTIAL” to “Janssen Pharmaceutical, Inc. CONFIDENTIAL”
- Left Footer (Page 2 to 6) changed from “© 2024 Janssen Biotech, Inc.” to “© 2021 – 2025 Janssen Pharmaceutical, Inc.”