

Cell Collection and Management Manual

Summary of Changes – updated to Version 6. December 2025

- Front page:
 - Cell Collection and Management Manual updated to Cell Collection and Management US Manual.
 - Version number and effective month/year updated.
- Page 2
 - Added “The requirements in this manual are intended to be incorporated into each treatment centre’s operating procedures or reference this manual as per treatment center’s procedure.”
 - Contents:
 - Updated contents table to include Abbreviations and Definitions of Terms
- Pages 2 to 7: Footer
 - Janssen Pharmaceuticals, Inc. CONFIDENTIAL updated to Confidential and Proprietary Information of Janssen Pharmaceuticals, Inc and moved to the left side of the footer.
 - The page number and TV-TEC-309939 v6 were added to the right side of the footer.
- Page 3
 - Abbreviations:
 - Col and CoC all capitalized throughout the manual
 - Definition of Terms:
 - Treatment Center Portal was updated to CQUENCE® TCP (Treatment Center Portal)
 - CoC/Col Portal was updated to CQUENCE® COI/COC Portal
- Page 4
 - Donation Eligibility for CARVYKTI®:
 - Step 1: “Confirm appropriate Donor Infectious Disease Testing was performed as required under all applicable laws” was updated to “Per treatment center procedures, confirm Donor Infectious Disease Testing was performed under all applicable laws.”
 - Printing Labels:
 - Step 3: Added “Label the collection bag with applicable warning label(s) per treatment center procedures” for improved clarity.
- Page 5
 - Cell Collection:
 - Step 4, first bullet: update the sentence to “if the site performs the pre-WBC cell count and it is...”
 - Step 5: (10 to 30 cm) was removed.
 - Step 6: “Any deviation from the manual should be documented and communicated to Janssen via treatment center’s procedures” was added to the note.
- Page 6
 - Step 8:
 - Acceptable apheresis tubing configuration picture was updated.
 - Cell Management and Transport
 - Step 1: “US” was added to Pack and Ship Manual reference
 - Step 2 “US” was added to Cell Cryopreservation Manual reference

- Step 4: “A post-collection donor health change notification should be required within one business day” was added per Quality Agreement.
 - Step 5: “Cryopreservation will be performed within 32 hours from the end of collection” was added for the treatment center’s awareness.
- Page 7
 - Version number was updated to Version 6