

Apheresis, Local Cell Lab, & Dual

Version 6.0

Chain of Identity & Custody

Managing Chain of Identity & Chain of Custody (COI/C)
Across the Advanced Therapies Order Fulfillment Process

Johnson&Johnson

Audience: Commercial

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1. Overview

What is the Chain of Identity/ Custody portal?

The Chain of Identity/Custody (COI/C) portal tracks the chain of identity and chain of custody hand-offs throughout the order fulfillment process by managing and verifying proper handling of the drug product.

The screenshot displays the Janssen Chain of Identity/Custody (COI/C) portal. The interface is titled "Role" and "Scheduled & In Process". It features a search bar with a "Search" button and a dropdown menu. Below the search bar is a table listing orders with columns for "Order/Subject ID", "COI ID", "Patient Name", "Lot Number", "Est. Delivery Da.", "Order Journey S.", "Status", and "Annotate".

Order/Subject ID	COI ID	Patient Name	Lot Number	Est. Delivery Da.	Order Journey S.	Status	Annotate
US-Test Clinical Orde4r	BIC.196111						
US-MSKCCS-WN90-1438	BIC.V16111						
EU-MSL-10129-NBMY-9900	BIC.NZ5111						
EU-MSL-10129-SXFG-8262	CLC.Z36111						
EU-MSL-10129-WCA6-0748	CLC.IU5111						
EU-DE-UNILEI-APH-01-861Y-2995	CLC.RV5111						
EU-DE-UNILEI-APH-01-861Y-2995	CLC.RV5111						
EU-MSL-10129-OTV4-4799	CLC.H36111						
EU-MSL-10129-OTV4-4799	CLC.H36111						

The right-hand side of the interface shows an "Order Overview" for a specific order. It includes a "Checklist" with items like "Collection", "Collection Data", "Infectious Disease Marker", "Collection Shipment", "Cryopreservation", "Manufacturing", and "Delivery". Below the checklist is a "Patient Verification" section with a table of patient details:

First Name	Middle Name	Last Name	Suffix
LTR	Patient	001	

Additional verification steps include "Confirmation" by the VZV Operator and "Verification" by BusinessAdmin MFG-1, both marked as completed.

Abbreviations

AWB	Airway Bill
COC	Chain of Custody (<i>not CoC, which is Certificate of Compliance</i>)
COI	Chain of Identity
COI/C	Chain of Identity/Custody
EQ	External Quality
DIN	Donor Identification Number
IDM	Infectious Disease Marker
NC	Non-Conformance
OKTA	(<i>Enterprise</i>) Identity Management Service
SEC-DIS	Single European Code Donor ID Sequence

Patient Identifier

In COI/C, you may be asked questions to enter in a patient identifier during your workflow. This is how the portal identifies if you have the correct order.

Different regions and countries use different identifiers. Please ensure that you refer to the most specific patient identifier for your country or region.



Country/Region	PII Field 1	PII Field 2
Australia	DIN	Apheresis ID
Belgium	SEC-DIS	
Brazil	DIN	Apheresis ID
Canada	DIN	Apheresis ID
Czech Republic	SEC-DIS	
Denmark	SEC-DIS	
France	SEC-DIS	
Germany	SEC-DIS	
Greece	SEC-DIS	
Israel	DIN	Apheresis ID
Italy	SEC-DIS	DIN
Japan	Apheresis ID	
Korea	Apheresis ID	
Netherlands	SEC-DIS	
Norway	SEC-DIS	
Poland	SEC-DIS	
Spain	SEC-DIS	
Sweden	SEC-DIS	
Switzerland	DIN	
UK	DIN	SEC-DIS
US	DIN	Apheresis ID



The Privacy Policy for the use of the COI/C Portal is available at the following link: [COI/C Privacy Policy](#).

Please read it carefully.

2. Login

The following section has screenshots that may vary slightly for your role and region.

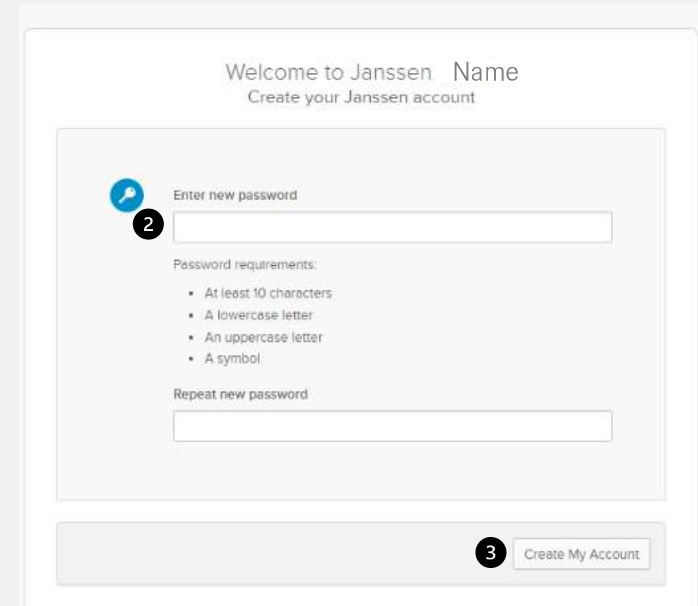
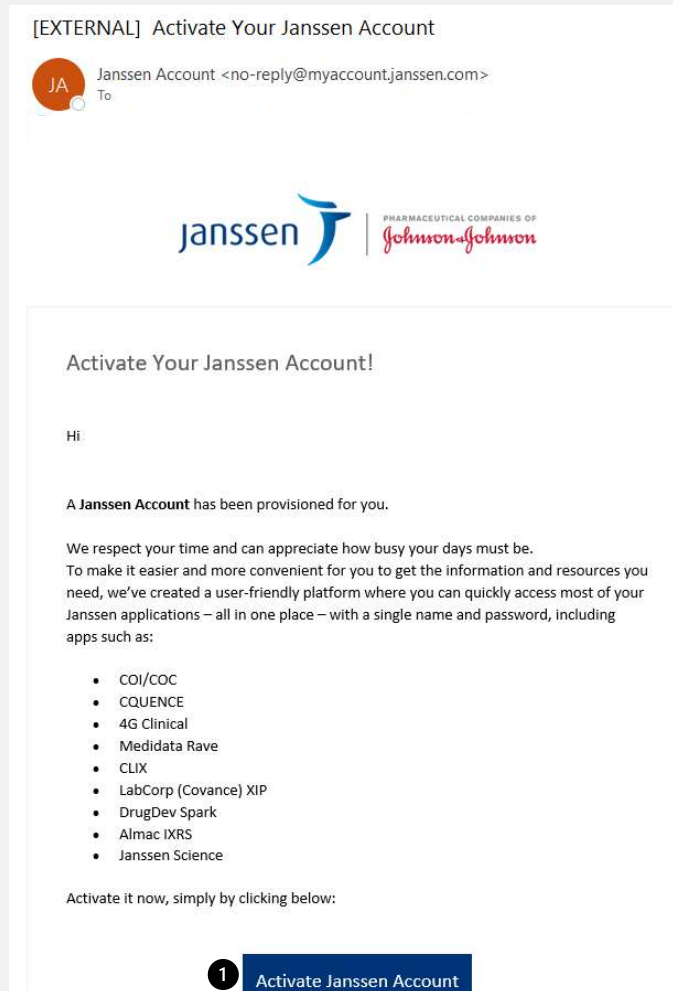
Activation

COI/C uses a sign-in software called OKTA. If you have an active OKTA account, you do not need to follow this process.

1. Within 30 days of receiving the activation email, press **“Activate Janssen Account”**.
2. Enter password twice.
3. Press **“Create My Account”**.

Note: If a user doesn't log into their account within 30 days, their account would be deactivated ; OKTA would then need to be contacted by your J&J representative

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Login

1. Enter email and press **“Next”**.
- ★ If you click “Keep me signed in”, you won’t need a code for the next 7 days after verifying (Step 3).
2. Enter password and press **“Verify”**.
3. Press **“Send me the code”**.
4. Copy code from email.
5. Enter the code and press **“Verify”**.

Important: After 30 minutes of inactivity, you will automatically be logged out

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The image displays a sequence of five screenshots illustrating the login process for a CQUENCE account:

- Step 1:** The user is prompted to "Sign in with your Janssen Account". They enter their email address in the "Email" field and click the "Next" button. A "Keep me signed in" checkbox is also visible.
- Step 2:** The user is prompted to "Verify with your password". They enter their password in the "Password" field and click the "Verify" button. Links for "Forgot password?" and "Back to sign in" are provided.
- Step 3:** The user is prompted to "Verify with Email Authentication". They click the "Send me the code" button to receive a verification code via email.
- Step 4:** The user receives an email titled "Janssen Account - One-time verification code". The email contains a greeting, a message stating "You are receiving this email because a request was made for a one-time code that can be used for authentication.", and a "Sign In" button. A code "117506" is displayed at the bottom.
- Step 5:** The user returns to the CQUENCE login page and enters the received code in the "Enter Code" field, then clicks the "Verify" button to complete the login process.

Reset Password

1. Press **“Forgot password?”**
2. Enter email or username.
3. Within 1 hour of receiving email, press **“Reset Password”**.
4. Enter new password twice.
5. Press **“Reset Password”**.

The image displays four sequential screenshots of the CQUENCE password reset process:

- Step 1:** The 'Sign in with your Janssen Account' page. It features fields for 'Email' and 'Password', a 'Sign In' button, and a red circle with the number '1' around the 'Forgot password?' link.
- Step 2:** The 'Reset Password' page. It has an 'Email or Username' input field and a 'Reset via Email' button. A red circle with the number '2' is placed over the input field.
- Step 3:** An email notification titled 'Janssen Account - Password Reset Requested'. It contains a 'Reset Password' button circled in red with a red circle and the number '3'.
- Step 4:** The 'Reset your password' page. It lists password requirements (at least 10 characters, lowercase and uppercase letters, and a symbol), fields for 'New password' and 'Repeat password', and a 'Reset Password' button circled in red with a red circle and the number '5'.

3. Portal Layout

The following section has screenshots that may vary slightly for your role and region.

3.1 Home

Home

Homepage: The most recent 300 Scheduled & In Process records

1. Press and select your desired **language**.
2. Press to return to **home** page.
 - ★ If you click the logo in the top left corner, it will also return you to home.
3. Press to view **reports**. The reports visible to you are dependent on your role and region.
4. Press to view **resource page**. The articles published related to your category will appear.
5. Press to view **notifications**. A red dot appears when a new notification is available.
6. Press to view your name or **log out**.
7. Enter desired order in **search** or **filter** by desired criteria before pressing “Apply All and Search”.
8. Your site’s in-progress and scheduled orders will appear here by default, unless you search or filter.
9. Press to view **all orders** for your site.

All orders not visible on home page are accessible within the ‘All Orders’ page.

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The screenshot displays the 'Role' page for 'Scheduled & In Process' orders. The page features a search bar and a table of orders. The table columns are: Order/Subject ID, COI ID, Patient Name, Lot Number, Est. Delivery Date, Order Journey Stage, Status, and Annotate. The table lists 15 orders with their respective statuses (In Process or Scheduled).

Order/Subject ID	COI ID	Patient Name	Lot Number	Est. Delivery Date	Order Journey Stage	Status	Annotate
EU-MSL-10129-5UB7-3901	CLCU26111	Watson Steele	QW476T		Manufacturing	In Process	
EU-MSL-10129-7Z92-9658	CLCC16111	Warren Rita	705550		Manufacturing	In Process	
US-MSKCCS-Y25G-9148	BIC736111	Ward Edwin			Manufacturing	Scheduled	
EU-MSL-10129-69ZQ-0911	BIC236111	Victoria Dakota			Manufacturing	In Process	
EU-MSL-10129-CCX9-9385	BIC826111	Toni Holly	759638		Manufacturing	In Process	
EU-MSL-10129-0YCF-8642	BIC266111	Tiffany Ortiz		Aug 06, 2025	Manufacturing	In Process	
EU-Clinical-Test-1909	BICWWS111	Test Clinical 1909			Manufacturing	In Process	
EU-Clinical-Test-M-010	BIC986111	Test Clinical 1	12345		Manufacturing	In Process	
EU-MSL-10129-2W6Y-4509	BICQ66111	Stone Hazel	567190	Aug 07, 2025	Manufacturing	In Process	
EU-MSL-10129-ZOC9-9218	BICE26111	Roy Katie			Manufacturing	Scheduled	
US-MSKCCS-03QZ-9454	CLCD26111	Rachael Jesse	QW476T		Manufacturing	In Process	
US-MSKCCS-L4FH-1882	BIC326111	Paul Herbert			Manufacturing	Scheduled	

Side Panel

1. To **open** the side panel, select the circle radio button (on the left-hand side) for the order you'd like to view.
2. Review the **patient and product information** to ensure you have selected the correct order.
3. Order Stage shows the progression of the order through its milestones. Press **“Proceed to Workflow”** to see your workflow or previously completed pages in your order journey.
4. Additional buttons may be available to you such as **Shipment Tracking** for quick links to shipment links or **All Summaries** to view completed workflows.

The screenshot displays the Janssen Role page. At the top, there is a search bar and a 'Search' button. Below the search bar is a table of orders with columns: Order/Subject, COI ID, Est. Delive., Lot Number, Order Journe., Status, and Annotate. The first row is selected, and a side panel is open on the right. The side panel shows the order details for EU-MSL-10129-9UBQ-1080, including Therapy (Cita-Cel), COI ID (CLCA76111), Lot Number (QW476T), and Patient Name (QW476T). The Order Stage section shows a vertical timeline with milestones: Collection, Complete EDM, Cryopreservation, Manufacturing, Finished Product at WDC, and Delivery. A 'Proceed to Workflow' button is visible at the bottom of the side panel. There are also 'Additional Options' like 'Shipment Tracking'.

Order/Subject	COI ID	Est. Delive.	Lot Number	Order Journe.	Status	Annotate
EU-MSL-10129-9UBQ-1080	CLCA76111	Nov 06, 2025	QW476T	Finished Product Delivery	Scheduled	
EU-MSL-10129-TF7-2855	CLCA66111	Nov 04, 2025	701100	Finished Product Delivery	Completed	
US-MSKCCS-QC8R-6699	CLC876111	Oct 13, 2025	548689	Finished Product Delivery	Scheduled	
US-MSKCCS-Q2H5-7501	CLC876111	Oct 13, 2025	504774	Finished Product Delivery	Scheduled	
US-MSKCCS-TROP-0933	CLC266111	Oct 13, 2025	277807	Finished Product Delivery	Scheduled	
US-MSKCCS-E8U-0592	CLCY56111	Oct 13, 2025	704646	Finished Product Delivery	In Process	
US-MSKCCS-4T5X-8627	CLCU56111	Oct 13, 2025	426425	Finished Product Delivery	In Process	
US-MSKCCS-EUTW-2437	CLCF56111	Oct 10, 2025	364372	Finished Product Delivery	In Process	
US-TESTCOM-Order-1	CLCYC6111	Oct 08, 2025	25HC1231	Collection	Scheduled	
N3AP10701H-PC001-02	CLCEA6111	Aug 25, 2025		Collection	Scheduled	IDM Pending
US-MSKCCS-Q1Q2-1278	CLCX55111	Aug 25, 2025	12345	Collection	In Process	
EU-MSL-10129-9UBQ-1080	CLCA76111	Aug 08, 2025	QW476T	Cryopreservation	In Process	Release Memo Pending

3.2 Navigation & Portal Functionality

Upper Page

1. The **title** of the page.
 - i. This is an example of the Collection Shipment page.
2. Review the **order overview** to confirm you have selected the correct order.
3. View the **checklist** to see the status of each section. Navigate to an available workflow page by pressing on its blue title.
4. Review the **patient and product information** to confirm that all information is correct. Contact your J&J representative if anything is incorrect.
5. Press **“Reprint Label”** to re-download a label that has been previously generated and signed for in a workflow.
6. Press **“Modify”** to edit a page. Select the reason for modification and press **“Continue Modification”**
 - i. Modification abilities are dependent on access type.

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The screenshot displays a web application interface for a 'Collection Shipment' page. The page is titled 'Shipment to Cryopreservation > Data Collection > Summary' and includes a 'Reprint Label' button and a 'Modify' button. The interface is divided into several sections:

- Workflow Name:** A dropdown menu showing 'Clinical-Bi-Car'.
- Order Overview:** A table with columns for 'Care Program', 'Order/Subject ID', and 'COI ID'. The data shown is 'Clinical-Bi-Car', 'US-UNIVHC-00test:1234', and 'BIC.KS5111'.
- Checklist:** A list of steps with status indicators: Collection (active), Collection Data, Infectious Disease Marker, Collection Shipment (active), Cryopreservation, Apheresis at WDC, World Distribution Center, Manufacturing, and Delivery.
- Patient Information: Test Upsert:** A form with fields for First Name, Middle Name, Last Name, Suffix, Date of Birth, Collection Date, Treatment Site, and Therapy/Product. The data shown is 'Test', 'Upsert', 'BIC.KS5111', and 'Bi-Car'.
- Transfer Product to Shipper:** A button to initiate the transfer process.
- Scan or Enter SEC-DIS on the apheresis bag:** A section for scanning or entering SEC-DIS information.

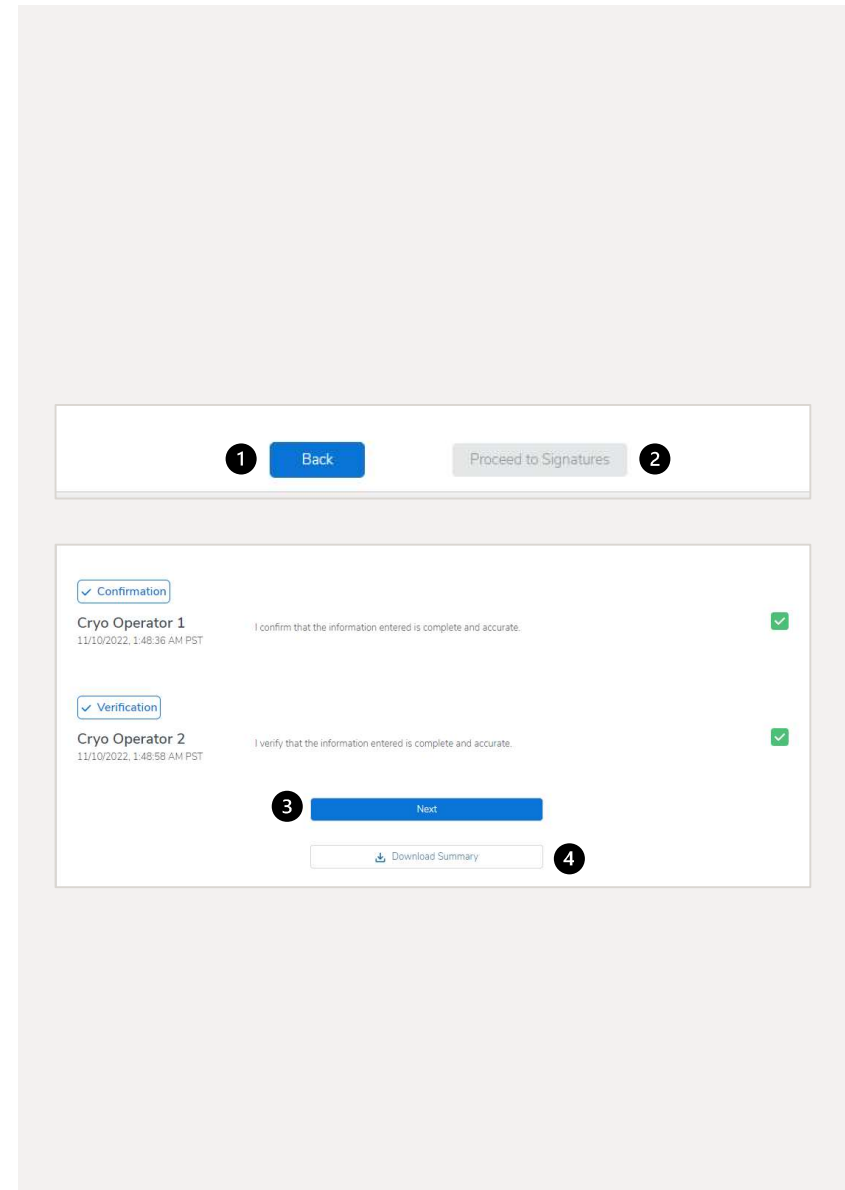
A dialog box titled 'Entering Modification Mode' is overlaid on the page. It contains the following text: 'Please confirm before proceeding to modify data. Note that if any signature has been provided when reviewing data entry, a reason for modification will be required. If no changes are made, please enter "No changes made".' Below this text is a dropdown menu with 'Select' as the current selection. A 'Continue Modification' button is visible at the bottom right of the dialog.

Lower Page

Scroll to the bottom of your workflow page to find these buttons.

1. If you can access multiple workflow pages, you may have a **“Back”** button available at the bottom of the page. This will bring you to the previous page or to the Home page.
2. If the workflow needs signatures, press **“Proceed to Signatures”** to reveal where to sign.
3. If you can access multiple workflow pages, you may have a **“Next”** or **“Proceed to Collection Shipment”** button available at the bottom of the page. This will bring you to the next page to be completed. If you have this button, press it to ensure that your workflow is completed.
4. If workflow is complete, press **“Download Summary”** to create a PDF version of the page.

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Label Generation

If the label did not generate as expected, follow Upper Page's instructions for "Reprint Label".

1. Press "**Generate Label**".
 - ★ If it is blocked, you must enable pop-ups.
 2. Press checkbox on.
- ★ **If blocked on Chrome:**
3. Press "Pop-up blocked".
 4. Press first circle.
 5. Press "Done".

The screenshot shows a web browser window with a 'Label Generation' page. At the top right, there is a 'Generate Label' button (1) with a star icon (★). Below it, a notification box (2) contains a checkbox labeled 'Packing Insert generated successfully' and a note: 'Please ensure packing insert is kept with the apherisis product as it will be included with the shipment out'. A 'Pop-up blocked' notification (3) is visible in the browser's address bar. A 'Pop-ups blocked' dialog box (4) is open, showing the URL 'https://cquencecoi...d/069Dy000002ejVqIAI' and two options: 'Always allow pop-ups and redirects from https://cquencecoic--qa.sandbox.my.site.com' (4) and 'Continue blocking' (selected). At the bottom of the dialog, there are 'Manage' and 'Done' buttons (5).

Signatures

1. Review all information entered on the page and press **“Confirm”**.
2. Enter your password and press **“Confirm”**.
3. A second person must review the information entered on the page. Once reviewed and confirmed that it is correct, press **“Confirm”**. It is important to confirm that the information is correct.
 - ★ The second person may log in from another computer to verify the information if they prefer not to use the same computer.
4. The second person needs to enter their email and password associated with the portal before pressing **“Confirm”**.

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The image displays a four-step process for signature confirmation:

- Step 1:** A "Confirmation" dialog box with a checkmark icon and a "Confirm" button. The text below the dialog reads: "I confirm that the information entered is complete and accurate."
- Step 2:** A modal window titled "Name : Role" with a close button (X). It contains a password input field labeled "Insert Password" and a "Confirm" button. The text below the dialog reads: "I, Name confirm that the information entered is complete and accurate."
- Step 3:** A "Verification" dialog box with a checkmark icon and a "Confirm" button. The text below the dialog reads: "I verify that the information entered is complete and accurate." Above the dialog, the text "Name" and "11/11/2022, 2:16:06 PM PST" is visible, along with a green checkmark icon.
- Step 4:** A modal window titled "Role" with a close button (X). It contains "Email" and "Password" input fields and a "Confirm" button. The text below the dialog reads: "I verify the identity of the patient has been verified."

3.3 Shipment Tracking

Shipment Tracking

1. Press “**Shipment Tracking**” in the Side Panel.
2. Review the Order Overview to ensure that you are viewing your desired order.
3. Find the desired part of the shipment journey and select the corresponding link:
 - Click ‘**View Tracking Information**’ to see standard tracking on the courier’s website
 - ★ • Click ‘**View Temperature & Tracking Report**’ (for Marken LN2 shipments) to view Temperature & Tracking Report.

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DE-TEST-GCC-123456 ✕

Therapy Cilta-Cel	Patient Name Percy Weasley	Date of Birth 2024-11-25
COI ID CLC.P35111	Lot Number N/A	

Order Stage

① Collection Complete IDM

○ Cryopreservation

○ Manufacturing

○ WDC

○ Delivery

[Proceed to Workflow →](#)

Additional Options

① [Shipment Tracking](#)

[Home](#) > [EU-TRT297-AUTO-8609](#) > Shipment Tracking

Shipment Tracking

[Order Overview](#)

② Order ID: EU-TRT297-AUTO-8609 COI Number: CLC.G82111

[Shipment Journey](#)

❄️ **Apheresis To Cryopreservation**

🧊 **Cryopreservation To Manufacturing**

📦 **Manufacturing To Distribution Center** [View Tracking Information](#) ③

Courier: World-LN2-Global-Mfg
Tracking ID: 712787267

🏠 **Distribution Center To Infusion Site** [View Tracking Information](#)

Courier: World-LN2-Global-Wdc
Tracking ID: 712787270

★ **Cryopreservation To Manufacturing** [View Tracking Information](#)

Courier:Marken-LN2-Inbound-EMEA
Tracking ID: 600X10899924

[View Temperature & Tracking Report](#)

4. Workflows

Roles



Apheresis

Tasks

- Infectious Disease Marker (outside of North America)
- Collection



Local Cell Lab

Tasks

- Ship material
- Receive final product

For sites that also perform local cryopreservation:

- Cryopreservation
- Release Memo



Dual

Tasks

- Infectious Disease Marker (outside of North America)
- Collection
- Ship material
- Receive final product

For sites that also perform local cryopreservation:

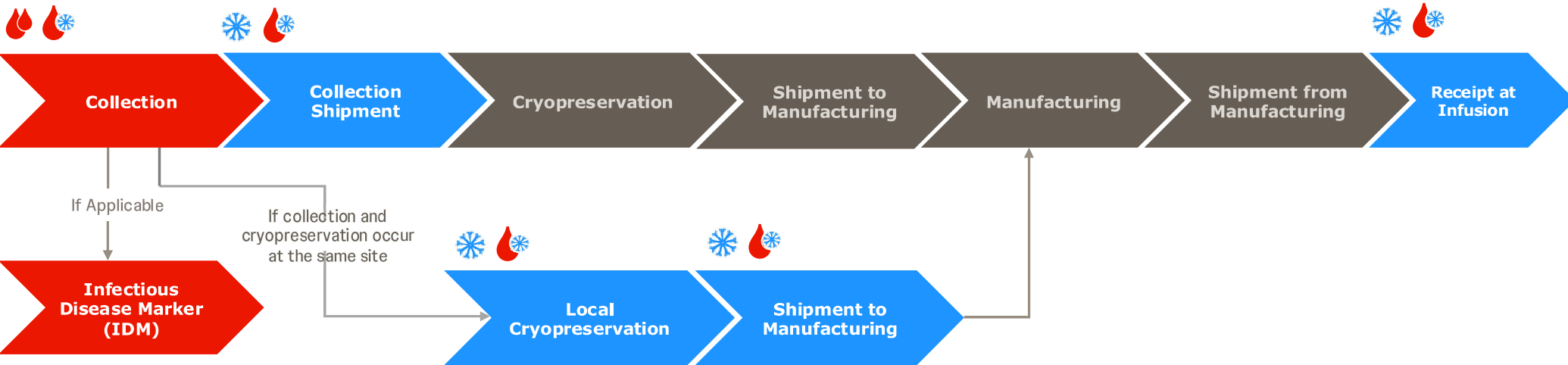
- Cryopreservation
- Release Memo

Process

Key

- Apheresis
- Local Cell Lab
- Other

Dual can complete both Apheresis & Local Cell Lab sections



4.1 Collection

 Apheresis

 Dual

Covers tasks related to patient apheresis.

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Collection

1. Follow 3.2's instructions for patient and product information as well as 3.2's instructions for signatures.
2. Enter the patient's weight in kilograms. Do not use commas.
3. Enter the collection date, its end time.

Note: The time zone will be automatically populated. You will need to reach out to the J&J representative to get it changed.

4. If the final Unique identifier will be entered at the Cell Lab press the checkbox. Steps 5 and 7 will be hidden, if selected.

• (Applicable primarily to the EMEA market) DIN/SEC-DIS/ Apheresis ID to be entered at Local Cell Lab

5. For sites with final unique identifier at collection, Enter your patient identifier twice and press **"Validate"**.
6. **"Submit"** the Collection Data section.
7. Review 3.2's instructions for label generation.
8. Follow 3.2's instructions for signatures.

Collection > Data Collection > Summary

Collection

Order Overview

Care Program: AU-Commercial-CLTACEL

Order/Subject ID: SG-SGDT20001-10344083-01

COI ID: CLC.F47111

You have completed this flow successfully and can now download the summary.

Checklist

- Collection
- Collection Data
- Infectious Disease Marker
- Collection Shipment
- Cryopreservation
- Manufacturing
- Delivery

1 Patient Verification: DERPM DUABZ

Verify patient name and date of birth using a Government issued identity Document

First Name	Middle Name	Last Name	Suffix
DERPM		DUABZ	

Date of Birth	Collection Date	Treatment Site	Therapy/Product
06 Apr 1973	18 Mar 2025	Peter MacCallum Cancer Centre	Chra Cel

Confirmation

Apheresis AU-PMACCC -APH-01 AU_01

I confirm the identity of the patient has been verified. 18 Mar 2025, 00:09:13 EDT

Verification

Apheresis AU-PMACCC -APH-01 AU_02

I verify the identity of the patient has been verified. 18 Mar 2025, 00:06:49 EDT

2 Collection Data

Patient Weight (in kg): 62

Time Zone: (GMT+11:00, Australian Eastern Daylight Time (Australia/Melbourne))

3 Collection Date: Mar 19, 2025

End of collection Time (24 h): 00:00

4 DIN/SEC-DIS/ Apheresis ID to be entered at Local Cell Lab

*Select Identifier: DIN

5 Scan or Enter DIN: 1234567890123

Validated on: 4/29/2025, 3:00:11 AM GMT+10

Number of Characters: 13

*DIN should be UNIQUE. Please modify the previously entered value, otherwise add detailed rationale and contact your local J&J representative.

6 Submit

7 Label Generation

Packing Insert/Shipper Label generated successfully

Yes

Please ensure packing insert/shipper label is kept with the apheresis product as it will be included with the shipment out.

8 Confirmation

Apheresis AU-PMACCC -APH-01 AU_02

I confirm that the information entered is complete and accurate. 28 Apr 2025, 13:08:28 EDT

Confirmation

I verify that the information entered is complete and accurate.

4.2 Infectious Disease Marker (IDM)

 Apheresis

 Dual

For sites outside of North America.\

Note: IDM is not Applicable to Japan orders, JCUU-34488

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Open IDM Page

1. To open the side panel, select the circle radio button on the order you'd like to view.
2. For regions where IDMs are a requirement, view the Annotate column of the desired order and look for **"IDM Pending"**.
Note: Regions where IDMs are not required will not see this option.
3. Review the patient and product information to ensure you have selected the correct order.
4. Press **"Complete IDM"**.

The screenshot shows the Janssen IDM Pending page. The interface includes a search bar at the top, a table of orders, and a detailed view of a selected order on the right. Numbered callouts 1-4 highlight key elements: 1. The radio button for selecting an order in the table. 2. The 'Annotate' column in the table header. 3. The 'IDM Pending' status in the table and the 'IDM Pending' header in the side panel. 4. The 'Complete IDM' button in the 'Order Stage' section of the side panel.

Order/Subj...	COI ID	Patient	Lot Number	Est. Deliver...	Order Jour...	Status	Annotate
<input checked="" type="radio"/> EU-MSL-10129-N8MY-9900	BIC.NZ5111	Yolanda Jack			Collection	In Process	IDM Pending
<input type="radio"/> EU-MSL-10129-RWAL-6576	BIC.PZ5111	White Derrick			Collection	In Process	IDM Pending
<input type="radio"/> EU-MSL-10129-4HAZ-3155	BIC.D86111	Wanda Kristine		Aug 12, 2025	Collection	In Process	IDM Pending
<input type="radio"/> EU-MSL-10129-5SPZ-0911	BIC.236111	Victoria Dakota			Collection	In Process	IDM Pending
<input type="radio"/> CH-3543636444-CLINICAL	BIC.NC6111	Victor Von Doom		Sep 20, 2025	Collection	Scheduled	IDM Pending
<input type="radio"/> CH-3543636234-CLINICAL-06	BIC.QC6111	Victor Von Doom		Sep 19, 2025	Collection	Scheduled	IDM Pending
<input type="radio"/> CH-3543636234-CLINICAL-05	BIC.PC6111	Victor Von Doom		Sep 19, 2025	Collection	Scheduled	IDM Pending

EU-MSL-10129-N8MY-9900

IDM Pending

Therapy: Bi-Car
COI ID: BIC.NZ5111

Subject Number: KVA1RTD33E
Lot Number: N/A

Patient Name: Yolanda Jack
Date of Birth: 1997-04-27

Order Stage

- Collection
- Complete IDM
- Cryopreservation
- Manufacturing
- Delivery


[Proceed to Workflow](#)

Additional Options

- Shipment Tracking

EMEA IDM

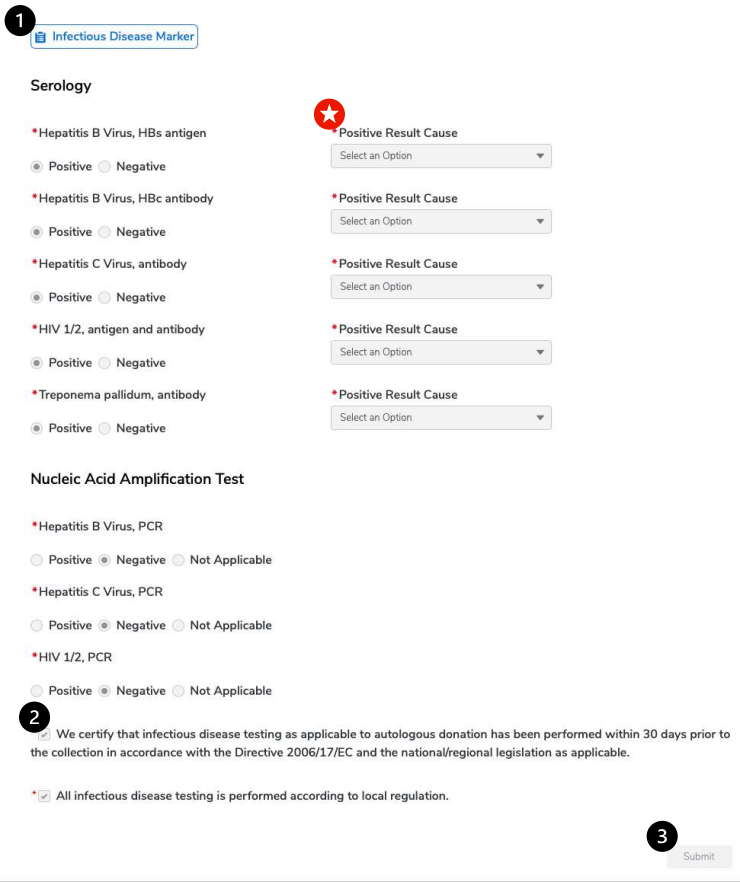
1. Select **‘Positive’** or **‘Negative’** for all required Hepatitis, HIV, and Syphilis markers under the Serology and Nucleic Acid sections.

 **Note:** If any result is marked ‘Positive’, you must select a valid reason from the ‘Positive Result Cause’ dropdown menu to proceed

2. Check the two mandatory boxes at the bottom of the form to certify that testing was performed in accordance with Directive 2006/17/EC and local regulations.

3. Click **Submit** to finalize the IDM record

Note: Electronic signatures will be prompted on the next screen.



The screenshot displays the EMEA IDM form interface. At the top, a tab labeled '1 Infectious Disease Marker' is visible. The form is divided into two main sections: 'Serology' and 'Nucleic Acid Amplification Test'. The 'Serology' section contains five rows of tests, each with radio buttons for 'Positive' and 'Negative' and a 'Positive Result Cause' dropdown menu. A red star icon is positioned above the first dropdown. The 'Nucleic Acid Amplification Test' section contains three rows of tests, each with radio buttons for 'Positive', 'Negative', and 'Not Applicable'. At the bottom of the form, there are two mandatory checkboxes: 'We certify that infectious disease testing as applicable to autologous donation has been performed within 30 days prior to the collection in accordance with the Directive 2006/17/EC and the national/regional legislation as applicable.' and 'All infectious disease testing is performed according to local regulation.' A 'Submit' button is located in the bottom right corner, marked with a '3' in a circle.

United Kingdom IDM

1. Select the patient's **Blood Type** from the dropdown menu and indicate the Rh Factor (Positive, Negative, or Unassigned).

2. Complete the Positive/Negative/Not Applicable radio buttons for all markers.

★ *Note: If any result is marked 'Positive', you must select a valid reason from the 'Positive Result Cause' dropdown menu to proceed*

3. Check the mandatory boxes to certify compliance with the 'Human Tissue Regulations 2007' and local regulation.

4. Click **Submit** to save the record.

5. Follow 3.2's instructions for signatures.

Infectious Disease Marker

1 *Blood Type
Select an Option
Please complete this field

2 *Rh Factor
 Positive Negative Unassigned/Undetermined

Serology

*Hepatitis B Virus, HBs antigen
 Positive Negative
Positive Result Cause: Select an Option
Complete this field.

*Hepatitis B Virus, HBc antibody
 Positive Negative
Positive Result Cause: Select an Option

*Hepatitis C Virus, antibody
 Positive Negative
Previous Infection
Chronic Infection
Vaccination
False Positive
Disease Under Control

*HIV 1/2, antigen and antibody
 Positive Negative

*Treponema pallidum, antibody
 Positive Negative

Nucleic Acid Amplification Test

*Hepatitis B Virus, PCR
 Positive Negative Not Applicable

*Hepatitis C Virus, PCR
 Positive Negative Not Applicable

*HIV 1/2, PCR
 Positive Negative Not Applicable

*HTLV-1 NAT
 Positive Negative Not Applicable

3 We certify that infectious disease testing as applicable to autologous donation has been performed within 30 days prior to the collection in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).

* All infectious disease testing is performed according to local regulation.

4 Submit

5 Proceed to Signatures

LATAM IDM

1. Select **'Positive'**, **'Negative'**, or **Not Applicable** for all required Hepatitis, HIV, and Syphilis markers under the Serology and Nucleic Acid sections.
2. Check the mandatory box at the bottom to certify that test were performed using products registered with ANVISA and in accordance with RDC 836/2023
3. Click **Submit** to finalize the record.

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Infectious Disease Marker

[Order Overview](#) In Process

Care Program: BR-Commercial-CLTACEL Order ID: LA-10021308-10245857-01 COI ID: CLC.WV811

Checklist

- Collection
- Collection Data
- Infectious Disease Marker**
- Collection Shipment
- Cryopreservation
- Manufacturing
- Delivery

Product Information

First Name	Middle Name	Last Name	Suffix
Michael		Scott	
Date of Birth	Collection Date	Treatment Site	Therapy/Product
2/29/1972	5/27/2025	REAL E BEMEMERITA ASSOCIAÇÃO PORTUGUESA DE BEEFICÊNCIA	Cita-Cel
MRN	1700924		

Infectious Disease Marker

Serology

*HCV: detection of anti-HCV antibody OR combined detection of anti-body + HCV antigen
 Positive Negative Not Applicable

*HBV: detection of antibodies against the HBV capsid - anti-HBc with research IgG + IgM
 Positive Negative Not Applicable

*HIV waste: detection of anti-HIV antibodies OR combined detection of antibodies against HIV + p24 antigen
 Positive Negative Not Applicable

*HTLV I and II infection: detection of anti-HTLV antibody HTLV I/II
 Positive Negative Not Applicable

*Chagas disease: anti-T cruzi antibody
 Positive Negative Not Applicable

*Syphilis: detection of anti-treponema or non-treponemal antibodies
 Positive Negative Not Applicable

*Malaria
 Positive Negative Not Applicable

Nucleic Acid Amplification Test

*HCV: detection of HCV nucleic acid
 Positive Negative Not Applicable

*HBV: detection of HBV nucleic acid
 Positive Negative Not Applicable

*HIV: detection of HIV nucleic acid
 Positive Negative Not Applicable

We certify all laboratory tests to detect markers of blood-transmitted infectious were carried out using in vitro diagnostic products registered with ANVISA for the purpose of screening donors, according to RDC 836/2023

Submit

APAC IDM

1. Complete the questions:
2. If a particular test is selected as 'Result Pending', the 'Expected Date for all pending results' field (#3) will present itself.
4. If a particular test is selected as 'Inconclusive/Indeterminate', you will see an 'Additional information for all inconclusive/indeterminate results' field (#5) appear

Infectious Disease Marker

[Order Overview](#) In Progress

Care Program: AU-Commercial-CITACEL | Order ID: AU-19484-20016286-01 | COI: CLC2E4112

- Collection
- Collection Data
- Infectious Disease Marker**
- Collection Shipment
- Cryopreservation
- Manufacturing
- World Distribution Center
- Delivery

Product Information			
First Name	Middle Name	Last Name	Suffix
John		Doe	
Date of Birth	Collection Date	Treatment Site	Therapy/Product
10/22/1995	07/25/2024	Stiflung Spital Muri	Cita-Cel

Infectious Disease Marker

Please complete the follow questions before apheresis material is picked up by courier. A late entrance of the information may lead to delayed receipt/processing of apheresis material at the cryopreservation center.

Serology

*Human Immunodeficiency Virus (HIV)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending

*Hepatitis B surface antigen (HBsAg)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending

*Hepatitis C Virus (HCV)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending

*Human T Lymphotropic Virus III (HTLV-III)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending

*Treponema Pallidum (Syphilis)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending

*Non-Treponema Pallidum (Syphilis)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending Not Applicable

*Cytomegalovirus Antibody (CMV Ab)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending Not Applicable

Nucleic Acid Amplification Test

*Human Immunodeficiency Virus (HIV)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending

*Hepatitis B Virus (HBV)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending

*Hepatitis C Virus (HCV)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending

*Cytomegalovirus (CMV)
 Non-reactive/Negative Reactive/Positive Inconclusive/Indeterminate Result Pending Not Applicable

Expected date for all pending results
Select a date...

Additional information for all inconclusive/indeterminate results

I certify that the patient infectious disease marker testing was performed in accordance with applicable local regulation.
 I certify that the CAR-T clinician is aware of the test results, and deems this patient eligible for autologous CAR-T therapy.

[Submit](#)

[Proceed to Signatures](#)

APAC IDM (Continued)

7. If a selection is marked as 'Not Applicable' (#A,B,C), a warning will present itself, prompting a confirmation.
8. *Not Shown:* Follow prior 3.2's instructions for signatures.

The screenshot displays a medical form interface with a dark background. A white dialog box titled "Country-Specific Guidance" is centered on the screen, containing the text: "This is a mandatory test for Korea, therefore, response cannot be Not Applicable." and a blue "Confirm" button. The dialog box is positioned over a form section titled "Serology".

The "Serology" section includes the following items:

- Human Immunodeficiency Virus (HIV) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending.
- Hepatitis B surface antigen (HBsAg) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending.
- Hepatitis C Virus (HCV) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending.
- Human T Lymphotropic Virus (HTLV-III) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending.
- Treponema Pallidum (Syphilis) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending.
- Non-Treponema Pallidum (Syphilis) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending. This item is marked with a red circle 'A' and "Not Applicable".
- Cytomegalovirus Antibody (CMV) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending. This item is marked with a red circle 'B' and "Not Applicable".

The "Nucleic Acid Amplification Test" section includes the following items:

- Human Immunodeficiency Virus (HIV) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending.
- Hepatitis B Virus (HBV) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending. This item is marked with a red circle 'C' and "Not Applicable".
- Hepatitis C Virus (HCV) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending.
- Cytomegalovirus (CMV) - Radio buttons for Non-reactive/Negative, Reactive/Positive, Inconclusive/Indeterminate, and Result Pending. This item is marked with a red circle 'C' and "Not Applicable".

Below the "Nucleic Acid Amplification Test" section, there is a field for "Expected Test Result Date" with a search icon, and a section for "Additional Information" with a text input area.

IDM Report

1. To pull a report, press the book icon, and select **“Infectious Disease Marker Testing”**.
2. Press the down arrow.
3. Select **“Infectious Disease Marker Testing”**.
4. View report.
5. Press **“Printable View”** to print or download.

The screenshot illustrates the user interface for generating an Infectious Disease Marker (IDM) report. It is divided into two main sections: a top navigation bar and a main content area.

Top Navigation Bar: Features a language dropdown set to 'English', a home icon, a book icon (labeled 1), a gear icon, a bell icon, and a user profile icon. A dropdown menu is open from the book icon, showing 'Upcoming Orders' and 'Infectious Disease Marker Testing' (highlighted with a red box).

Main Content Area: The 'Recently Viewed' section (labeled 2) shows a list of views: 'Infectious Disease Marker Testing' (labeled 3), 'Orders - VP', and 'Recently Viewed (Pinned list)'. Below this, the 'Infectious Disease Marker Testing' report is displayed (labeled 4). The report header includes the Janssen logo, language dropdown, and navigation icons. A search bar and 'Printable View' button (labeled 5) are also present. The report content shows 50+ items, sorted by COI ID, with columns for COI ID, Order Id, Patient, COI C..., Receipt at Cryo..., Canc..., and Annotate. The table lists 16 items, each with a status of 'IDM Pending' and a dropdown arrow.

COI ID	Order Id	Patient	COI C...	Receipt at Cryo...	Canc...	Annotate
1	CLC.186111 EU-MSL-10121-RBG1-4565	King Evan	Collection	22.04.2025, 02:07	<input type="checkbox"/>	IDM Pending
2	CLC.193111 EU-12469-20017240-01	OOS_2 Exploratory Testing	Collection	09.05.2024, 05:00	<input type="checkbox"/>	IDM Pending
3	CLC.1A3111 EU-TRT-intSR-05082	Jimmy Matt	Collection	20.05.2024, 05:00	<input type="checkbox"/>	IDM Pending
4	CLC.1B6111 EU-MSL-10121-T72J-4697	Steele Tammy	Collection	22.04.2025, 23:01	<input type="checkbox"/>	IDM Pending
5	CLC.1C3111 EU-TRTTST-UAT-03	Piers Morgan	Collection	24.06.2024, 05:00	<input type="checkbox"/>	IDM Pending
6	CLC.1D2111 EU-14027-20016274-01	ColCoC4UAT TestGermanyPatient140	Collection	27.12.2023, 04:00	<input type="checkbox"/>	IDM Pending
7	CLC.1D4111 EU-MSL-10129-test-3213	Rafael Ruben	Collection	19.11.2024, 02:11	<input type="checkbox"/>	IDM Pending
8	CLC.1D6111 EU-TRT-GB-25529-L42C-9976	Tonya Robbins	Collection	23.04.2025, 04:48	<input type="checkbox"/>	IDM Pending
9	CLC.1F2111 EU-12469-20016188-02	AHVP-1882_New1 UAT Core	Collection	21.10.2023, 05:00	<input type="checkbox"/>	IDM Pending
10	CLC.1G2111 EU-WV29912-test-7774	Melinda Arthur	Collection	21.11.2023, 08:31	<input type="checkbox"/>	IDM Pending
11	CLC.1H6111 EU-TRT-GB-25529-Y6T4-3936	Christie Barry	Collection	25.04.2025, 00:56	<input type="checkbox"/>	IDM Pending
12	CLC.1I1111 EU-TESTDE-LTRDE011-01	Patient 15	Collection	31.05.2023, 03:00	<input checked="" type="checkbox"/>	IDM Pending
13	CLC.1I3111 EU-12469-20017552-01	Expl Testing DE Backup	Collection	04.07.2024, 05:00	<input type="checkbox"/>	IDM Pending
14	CLC.1J3111 EU-103228-20017657-01	AHVP-2511_New UAT R6.1	Collection	18.07.2024, 05:00	<input checked="" type="checkbox"/>	IDM Pending
15	CLC.1K6111 EU-MSL-10121-ESSA-6085	Laverne Stanley	Collection	28.04.2025, 09:16	<input checked="" type="checkbox"/>	IDM Pending
16	CLC.1M5111 EU-MSL-10121-VSOL-1336	Ora Paulette	Collection	20.02.2025, 23:30	<input type="checkbox"/>	IDM Pending

4.3 Collection Shipment

 Local Cell Lab

 Dual

Covers tasks related to shipment if the order will be cryopreserved at a different location.

J&J

4.4 Local Cryopreservation

 Local Cell Lab

 Dual

Covers tasks related to cryopreservation when it occurs at the same site as collection. This section is not applicable outside of North America.

J&J

Local Cryopreservation

1. Follow 3.2's instructions for patient and product information.
2. Scan or enter patient identifier and press **“Submit”**.
3. Enter number of bags and date cryopreserved. Press **“Submit”**.
4. For each cryopreserved bag, scan or enter the patient identifier on the bag, patient identifier on the cassette, bag identifier, and the bag's total volume in milliliters (mL). Validate the patient identifier fields.
5. Review and verify the previously entered information before pressing the checkbox. Press **“Submit”**.
6. Follow 3.2's instructions for signatures.

The screenshot displays the 'Cryopreservation' web application interface. At the top, it shows the 'Order ID' (EU-MSL-10121-PNE-4787) and 'COI ID' (CLC.2H7.111). A checklist on the left indicates the current step is 'Cryopreservation'. The main form is divided into several sections:

- Product Information:** Fields for First Name (Vega), Middle Name, Last Name (Catherine), and Suffix. A table for Date of Birth (2/26/2024), Date & End Time of Collection (3/26/2025, 7:04:00 PM PDT), Therapy/Product (Cita-Cel), and Treatment Site (Universitätsklinikum Leipzig AoR, GMP-Labor). Another table for SEC-DIS (46553007251593141535), Patient Weight (28 kg), Collection Site (Universitätsklinikum Leipzig AoR, GMP-Labor), and Cryopreservation Site (Hautunorzentrum Leipzig).
- Verify the Patient:** A section with a 'Submit' button and a validation message: '* Scan or Enter SEC-DIS to verify the patient'.
- Cryopreserved Bags:** A table with columns for 'Number of Bags formulated for Cryopreservation' (2) and 'Cryopreservation Date' (Jun 5, 2025). A 'Submit' button is present.
- Cryopreservation Data:** Two sections for 'Bag 1' and 'Bag 2'. Each section has fields for 'Scan or Enter SEC-DIS on cryopreserved Bag' (with validation messages), 'Enter Bag Identifier for Bag (e.g. A1, B1, C1, D1)', and 'Total Volume (in mL) (Cells + CS10)'. Each row includes a 'Validate' button.
- Confirmation:** A section with a 'Confirm' button and a message: 'I confirm that the information entered is complete and accurate.'
- Verification:** A section with a 'Confirm' button and a message: 'I verify that the information entered is complete and accurate.'

4.5 Shipment from Cryopreservation

 Local Cell Lab

 Dual

Covers tasks related to the shipment of the cryopreserved material to a manufacturing site. This section is not applicable outside of North America.

J&J

Shipment from Cryopreservation

1. Follow prior 3.2's instructions for patient and product information.
2. Follow prior 3.2's instructions for generating a label.

Shipment From Cryopreservation > Data Collection > Summary Reprint Label Modify

Shipment From Cryopreservation

Order Overview Completed

Care Program: US-Commercial-CLTACEL Order/Subject ID: US-BAKARM-10264753-01 COI ID: CLC.WLH111

You have completed this flow successfully and can now download the summary

Checklist

- Collection
- Collection Shipment
- Cryopreservation
- Receipt at Cryo
- Cryopreservation
- Shipment From Cryopreservation
- Release Memo
- Manufacturing
- Delivery

1 Product Information

First Name	Middle Name	Last Name	Suffix
Patient ATSM		xKmDC	
Date of Birth	Date & End Time of Collection	Therapy/Product	Treatment Site
05 Sep 1991	23 Jan 2026, 00:04:00 EST	CiTa-Cel	Karmanos Cancer Center
DIN	Patient Weight (In kg)	Collection Site	Cryopreservation Site
1781781781781	60	Barbara Ann Karmanos Cancer Institute	HOWORTH BLOOD CENTER - CELL THERAPY

2 Shipment Selection

COI Bag ID	Total Volume	Ship Bags
CLC.WLH111C.01	10	Ship
CLC.WLH111C.02	10	Don't ship
CLC.WLH111C.03	20	Don't ship

2 Label Generation

Packing Insert/Shipper Label generated successfully
Yes Generate Label

Shipment from Cryopreservation (Continued)

3. Enter and **Validate** the Transfer to Product Shipper information.
4. Enter the Shipment Checkless information and complete and mandatory follow-up questions prompted by your selection.
5. *Not Shown:* Follow prior 3.2 instructions for signatures.

The screenshot displays a web application interface for shipment tracking, divided into two main sections: Step 3 and Step 4.

Step 3: Transfer Product to Shipper

IMPORTANT: Please place the finished product into the LN2 shipper as soon as possible and ensure all checks have been performed and verified. The frozen bag is fragile. Always handle the cassette with frozen bag with care and maintain control at all times.
Remove cassette from storage and scan the COI bag ID to capture the time of this step. Next, transfer the cassette into the LN2 shipper and scan the COI number on the packing insert/shipper label to capture the time of this step.

Bag 1 - Identify Labels that end with C.01

* Scan or Enter COI Bag ID as each cassette is transferred to shipper

BICAD6111.C.01 Validated on 9/22/2025, 10:23:07 AM PDT

* Scan or Enter COI on the Packing Insert/Shipper Label

BICAD6111 Validated on 9/22/2025, 10:23:42 AM PDT

Bag 3 - Identify Labels that end with C.03

* Scan or Enter COI Bag ID as each cassette is transferred to shipper

BICAD6111.C.03 Validated on 9/22/2025, 10:24:11 AM PDT

* Scan or Enter COI on the Packing Insert/Shipper Label

BICAD6111 Validated on 9/22/2025, 10:24:20 AM PDT

Cassettes have been transferred to LN2 shipper

Step 4: Shipment Checklist

* Scan or Enter House Air Waybill Number

210820107W Validated on 9/22/2025, 8:35:17 PM PDT

* Is the shipping container case intact? If the shipping container is damaged or not in expected condition, please contact your Johnson & Johnson representative for further instructions.

Yes No

* Was there a temperature out-of-range alarm received? If yes, please contact your Johnson & Johnson representative immediately and do NOT proceed until further instructions are given

Yes No

* Confirm cryopreserved apheresis product cassette were not exposed to ambient temperature greater than 3 minutes

Yes No

* Is the Red Wire Tamper Seal labeled "RACK" in place on the cassette rack?

Yes No

* Is the Red Wire Tamper Seal attached to the LN2 shipper lid?

Yes No

* Is the Consignee kit pouch included with the shipper?

Yes No

* Is the packing insert/shipper label included with the shipper?

Yes No

* Enter the last 4 digits of the EVO-IS Number on the LN2 shipper lid

1234

* Does the EVO-IS Number listed on the House Air Waybill match the EVO-IS Number on the LN2 shipper lid?

Yes No

* Enter the Tamper Seal Number attached to the LN2 shipper lid

1234

* Does the Tamper Seal Number listed on the House Air Waybill match the Tamper Seal Number attached to the LN2 shipper lid?

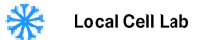
Yes No

* Is the shipping container case secured with a zip tie?

Yes No

Enter comments or issues (missing items, mismatching numbers, typos, damage, temperature out-of-range, etc.) of the shipment. Please do not enter patient personal information, product quality complaints, or other health hazards in this field. Please contact your Johnson & Johnson representative if these events occur. (optional)

4.6 Release Memo



(Only for sites trained by J&J to perform cryopreservation)

Covers tasks related to Certificate of Compliance and Authorization for Further Processing of Cryopreserved Apheresis Material through the verification of process parameters and batch disposition. This section is not applicable outside of North America.

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Open Release Memo Page

1. To open the side panel, select the circle radio button on the order you'd like to view.
2. To identify an order with an incomplete Release Memo, view the Annotate column of the desired order and look for **“Release Memo Pending”**.
3. Review the patient and product information to ensure you have selected the correct order.
4. Press **“Complete Release Memo”**.

The screenshot displays the Janssen release memo interface. At the top, there is a search bar and a navigation menu. Below the search bar, a table lists various orders with columns for Order/Subject, COI ID, Est. Delive., Lot Number, Order Journe..., Status, and Annotate. The table contains 14 rows of data, with the first row highlighted. A side panel on the right provides detailed information for the selected order, including Therapy, COI ID, Subject Number, Lot Number, Patient Name, Date of Birth, Order Stage, and Additional Options. The Order Stage section shows a flowchart with steps: Collection, Complete IDM, Cryopreservation, Complete Release Memo, Manufacturing, and Delivery. The 'Complete Release Memo' step is highlighted with a red circle and the number 4. The 'Proceed to Workflow' button is also visible.

Order/Subject	COI ID	Est. Delive.	Lot Number	Order Journe...	Status	Annotate
U550001L-BL01-01	BICJF6111	Oct 17, 2025	4555	Cryopreserva-tion	In Process	Release Memo Pending
U550001L-BL02-01	BCM.MF6111	Oct 15, 2025	6543	Cryopreserva-tion	In Process	Release Memo Pending
O30L90011LA-BELD02-01	BCM.DF6111	Oct 11, 2025	1234	Cryopreserva-tion	In Process	Release Memo Pending
O30G-B80001LA-BELD09-01	BICJF6111	Oct 10, 2025	5656	Cryopreserva-tion	In Process	Release Memo Pending
N30U510406LA-BELD09-01	BCM.QE6111	Oct 10, 2025	Q12345	Cryopreserva-tion	In Process	Release Memo Pending
R.60001BLD1-01	BCM.MF6111	Oct 08, 2025	1234	Cryopreserva-tion	In Process	Release Memo Pending
N30U510406M-P005-01	BIC.ZD6111	Oct 08, 2025	1425100052	Cryopreserva-tion	In Process	Release Memo Pending
BV7G-B80001LA-BEL001-01	BIC.9F6111	Oct 01, 2025	1234	Cryopreserva-tion	In Process	Release Memo Pending
N30L10701AA002-01	BIC.LD6111	Sep 30, 2025		Cryopreserva-tion	In Process	Release Memo Pending
N30E10407A.AQ01-01	BIC.KD6111	Sep 26, 2025		Cryopreserva-tion	In Process	Release Memo Pending
K12U510401-COC002-01	BCM.GD6111	Sep 25, 2025	9999	Cryopreserva-tion	In Process	Release Memo Pending
K12U510401-COC001-01	BCM.ED6111	Sep 25, 2025	1234	Cryopreserva-tion	In Process	Release Memo Pending

Release Memo

1. Follow 3.2's instructions for patient and product information.
2. Enter all parameters for each bag, ensuring you match the requested format, to certify the compliance of the cryopreserved apheresis. Press **"Submit"**.
3. Enter the answers associated with the Batch Disposition and press **"Submit"**.
4. *Not Shown:* Follow 3.2's instructions for signatures.

The screenshot shows a 'Release Memo' form with several sections. Callout 1 points to the 'Product Information' section, which includes fields for Patient Name (First, Middle, Last, Suffix), Date of Birth, Date & End Time of Collection, Therapy/Product, Treatment Site, SEC-DIS, Patient Weight (in kg), Collection Site, and Cryopreservation Site. Callout 2 points to the 'Process Parameters' section, which contains a table of parameters for each bag. Callout 3 points to the 'Batch Disposition' section, which includes several yes/no questions.

Parameters	PAR	*Bag 1 (Actual Value)
Automatic Pre-Process Holding (minutes)	< 30.00	14.00
Centrifuge (G)	300 - 400	000
Centrifuge Temperature (°C)	14 - 24	00
Centrifuge Time (min) - (normal 3.5x centrifuge minutes x 2) (minutes)	17 - 20	000
ES 50 percentage of final formation (%)	40 - 60	00
Total White blood cell (WBC) (Bag in 10 ⁶ units)	1.0 - 7.0	000
CR200 fill volume (mL)	50 - 70	00
ES10 Exposure time (min)	< 00:05 (HH:MM)	provide
Process time (hour)	< 04:00	provide
Transfer time (min) - (normal 3.5x centrifuge minutes x 2) (minutes)	< 2	000
Liquid Nitrogen 3.02G Storage Temperature (°C)	< -120	<input type="checkbox"/> Meet <input type="checkbox"/> Does Not Meet
Cryoprotectant Batch Process (CP) profile	in accordance with Profile Batch Record (BR)	<input type="checkbox"/> Meet <input type="checkbox"/> Does Not Meet
Characterization due to environmental responsibility (in kg) (per patient, each bag, each bag, aggregate total) (kg)	No characterization	<input type="checkbox"/> Meet <input type="checkbox"/> Does Not Meet
Temperature out of Range (TOR) (°C) observed during the transportation from the cell collection site to CPC	No Temperature out of Range (TOR) (°C) observed during the transportation from the cell collection site to CPC	<input type="checkbox"/> Meet <input type="checkbox"/> Does Not Meet

Batch Disposition

1. Select **"Yes"** if any of the Process Parameters are out-of-range or “Does not Meet” was selected, otherwise select **"No"**.
2. Select **"Yes"** if site is qualified for delegate batch record review, otherwise select **"No"**.
3. Select **"No"** if site answered “Yes” to #1 or “No” to #2 due to any major or critical deviation requiring an external quality assessment, otherwise select **"Yes"** if site is comfortable to release the material.
4. Select **"Yes"** if site is in Germany, otherwise select **"No"**.
5. *For EMEA only:* Select **"Yes"** if there was a major or critical deviation during the process, otherwise select **"No"**.

J&J

Batch Disposition

1 * Was there excursion from "Process Parameters" section?

Yes

No

2 * Is the site qualified for delegated batch record review?

Yes

No

3 * Released.

Yes

No

4 * Is the Cryopreservation Centre (CPC) from Germany?

Yes

No

5 * Was there a major/critical deviation?

Yes

No

4.7 Receipt at Infusion Site

 Local Cell Lab

 Dual

Covers tasks related to receiving the final product at the infusion site.

J&J

Receipt at Infusion Site

1. Follow 3.2's instructions for patient and product information.
2. Verify that the bags shipped match what was selected from the previous site and press **“Submit”**.
3. Scan or enter the COI on the packing insert.
4. Enter the shipping information. If an unfavorable answer is selected, you must answer a mandatory follow-up question.
 - ★ **Important:** You must click the 'validate' button. This captures a critical timestamp that is used to verify temperature data.
 - ★ **Important:** If the EVO-IS or Tamper Seal Number do not match what is expected from the previous site, you must reach out to a J&J representative.
5. Enter the correct shipping information and submit section.

Receipt at Infusion Site > Data Collection

Receipt at Infusion Site

Order Overview

Care Program: DE-Commercial-CLTACEL

Order/Subject ID: EU-MSL-10121-KPRZ-6580

COI ID: CLC.RL7111

Checklist: Collection, Cryopreservation, Manufacturing, Delivery, Receipt at Infusion

1 Product Information

First Name, Middle Name, Last Name, Suffix

Date of Birth: 27 Mar 2025

Collection Date: 27 Mar 2025

Therapy/Product: Cita-Cel

Treatment Site: Universitätsklinikum Leipzig AöR, GMP-Labor

SEC-DIS: 571754859527524125788

Lot Number: 916409

SEC-PI5: A005241000120250427

2 Shipment Selection

COI Bag ID	Lot Number	Total Volume	Ship Bags
CLC.RL7111.F01	916409	70mL	Ship

3 Shipment Receipt Checklist

* Scan or Enter the COI found on the LN2 packing insert/shipper label

Validate

4 * Enter the last 4 digits of the EVO-IS Number on the LN2 shipper lid

Validate

* Enter the Tamper Seal Number attached to the LN2 shipper lid

Validate

5 * Is the shipping container case intact? If the shipping container is damaged or not in expected condition, please contact your Johnson & Johnson representative for further instructions.

Yes No

* Is the shipping container case secured with a zip tie?

Yes No

* Was there a temperature out-of-range alarm received? If yes, meaning a Temperature Out-of-Range (TOR) has occurred, proceed with the unpacking immediately and then follow the TOR procedures outlined in the manual.

Yes No

* Is the Consignee kit pouch included with the shipper?

Yes No

* Is the packing insert/shipper label included with the shipper?

Yes No

* Does the EVO-IS Number listed on the House Air Waybill match the EVO-IS Number on the LN2 shipper lid?

Yes No

Receipt at Infusion Site (Continued)

6. Enter the correct product information and submit section.

7. Follow 3.2's instructions for signatures.

★ Canada-Only: Once Local QA completes the local quality decision workflow, Local Cell Lab Operators associated to the treatment site will be notified of the decision via email.

The screenshot shows a 'Product Receipt Checklist' form with the following sections:

- Section 6:** A checklist with four questions, each with 'Yes' and 'No' radio buttons.
 - Question 1: "Is the packing insert/shipper label included with the shipper?"
 - Question 2: "Is the Red Wire Tamper seal attached to the LN2 shipper lid?"
 - Question 3: "Does the EVO-IS Number listed on the House Air Waybill match the EVO-IS Number on the LN2 shipper lid?"
 - Question 4: "Does the Tamper Seal Number listed on the House Air Waybill match the Tamper Seal Number attached to the LN2 shipper lid?"
- Section 7:** A checklist with four questions, each with 'Yes' and 'No' radio buttons.
 - Question 1: "Confirm product cassette were not exposed to ambient temperature greater than 3 minutes."
 - Question 2: "Is each bag and cassette in the expected condition (e.g., no cassette damage, label adhered)? If bag or cassette is not in expected condition, please contact your Johnson & Johnson representative for further instructions"
 - Question 3: "Was the tamper evident seal in place on the cassette rack?"
 - Question 4: "Has the CAR-T product been placed into storage as per the cassette label: Store at s-120°C (-184°F), vapor phase of LN2? (Always proceed with product storage regardless of the shipment conditions)"

Below the checklist is a text area for comments: "Enter comments or issues (missing items, mismatching numbers, typos, damage, temperature out-of-range, etc.) of the shipment. Please do not enter patient personal information, product quality complaints, or other health hazards in this field. Please contact your Johnson & Johnson representative if these events occur. (optional)".

At the bottom, there are "Back" and "Proceed to Signatures" buttons, with a "Submit" button at the top right of the form area.

5. Exceptional Scenarios

5.1 Paper Processes



Apheresis



Local Cell Lab

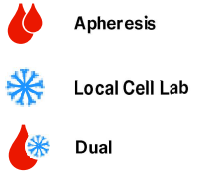


Dual

Covers tasks related to completing your work on paper.

J&J

Paper Processes



Why?

Moving to a paper process when errors occur allows you to continue your work while minimizing potential delays to guarantee chain of identity/custody.

When?

- Inaccurate patient information has been identified and is past the stage to edit it.
- Portal is malfunctioning and not working as you expect it to.
- Previous workflow is paper-based.

How?

1. Contact your J&J Representative immediately when initiating the paper-based process.
2. Open your file sharing tool. Johnson & Johnson users will use TruVault. External users will use MBOX.
3. Download the corresponding form on the file sharing tool.
4. Complete the form and upload it to the file sharing tool on the same day.

5.2 Second Bag Delivery



Local Cell Lab



Dual

Covers tasks related to when an additional final product bag is needed after the initial shipment to the infusion site has been completed.

J&J

Second Bag Delivery

1. Identify the order with the tag “**Second Bag Delivery**” in the Annotate column.

Can leverage filters to search for Second Bag Delivery.

2. Complete a second Receipt at Infusion workflow page.

J&J

The screenshot displays the Janssen system interface. At the top right, there are logos for 'Local Cell Lab' (a blue snowflake) and 'Dual' (a red blood drop with a blue snowflake). A 'Filters' modal is open in the center, showing dropdown menus for 'Case Status' (Completed; In Process; Scheduled; Cancelled), 'Business' (Clinical; Commercial), and 'Annotate' (Second Bag Delivery). Below the filters are 'Apply' and 'Clear Filter' buttons. The main interface shows a search bar with 'Search' and 'All Orders' buttons. Below the search bar is a table with the following data:

Order/Subject ID	COI ID	Patient Name	Lot Number	Est. Delivery ... ↑	Order Journey S...	Status	Annotate
N34JP10701H-PC001-01	BCM.5A6111	*	1234F56	Sep 02, 2025	Manufacturing	In Process	Second Bag Delivery ¹

At the bottom of the table, it says '1 Results' and has a pagination control showing '1'.

6. Change Log

End of Document

(Document Revision History)

Version Number	Section	Description of Change	Justification of Change
9.0	10	Added portal timeout information	CQUENCE Cell Management Release 6.0
	27	Updated Collection page to reflect time zone as read-only and included screenshot of new view	
	4, 14, 15, 29, 43, 52	Updated landing page screenshots	
	24	Changed the design for the role slide	
	27	Updated time zone comment	
	30	Updated screenshot for EMEA IDM questions	
	34	Updated screenshot for APAC IDM	
	32	Updated screenshot for UK IDM questions	
31	Updated Step Verbiage in EMEA IDM		