Bristol Myers Squibb™

Celgene | Cell Therapy 360™

Adult MNC Collection Procedure

North America

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Digital MNC Collection Procedure Navigation

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To return to the previous place after clicking a link or button, hold the Alt key and press the left arrow for a PC, or hold the Command key and press the left arrow for a Mac.

The functionality of this interactive PDF collection procedure is limited when using a web browser. For the best viewing experience, use Adobe Acrobat.

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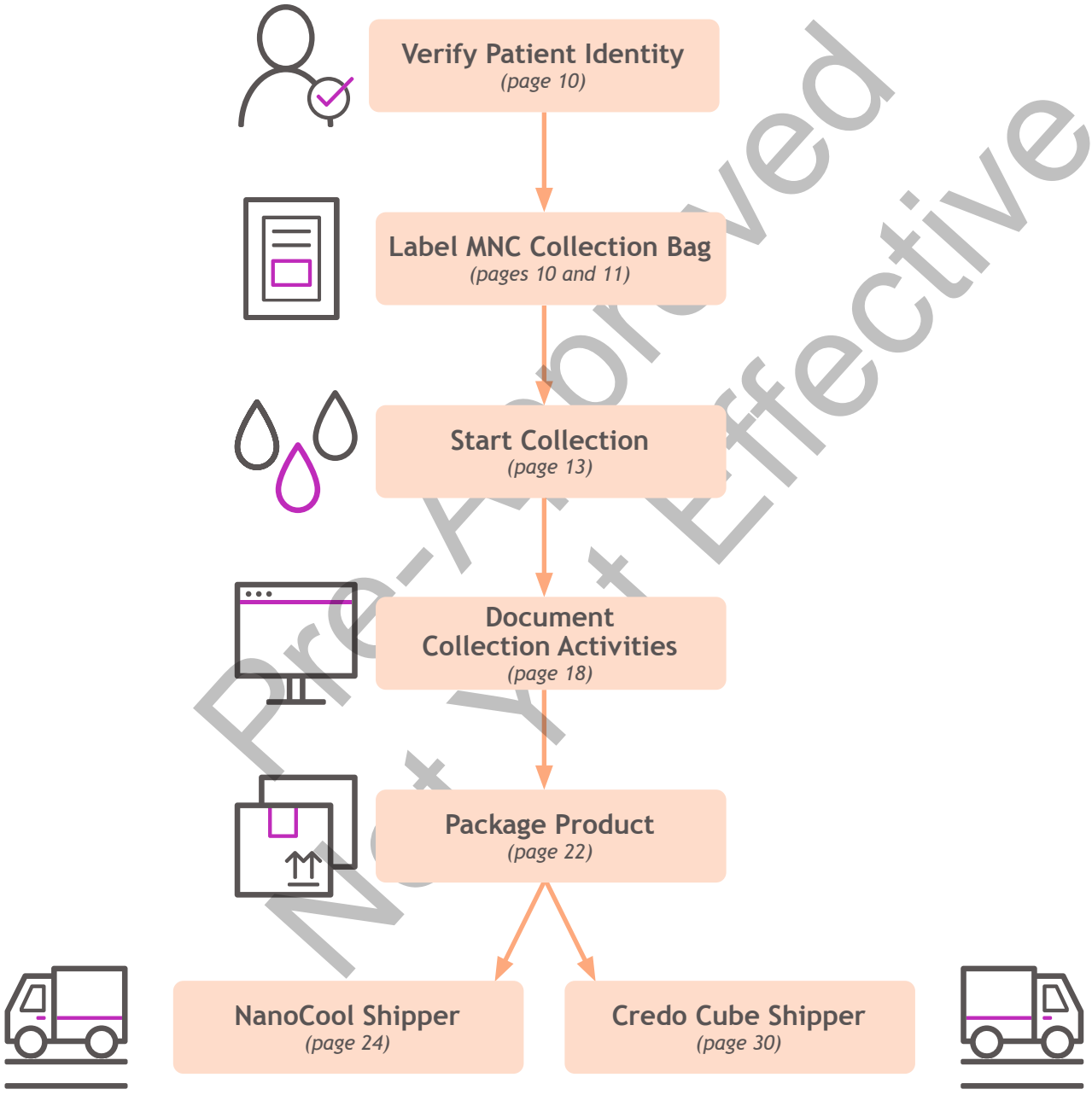
Day of Collection Workflow Guide

Click on a step to go directly to that section.



1. Introductory Information

1.1 Purpose

This collection procedure defines the process for performing and packaging non-mobilized autologous mononuclear cell (MNC) collections. MNC Product specification requirements are defined within this procedure.

1.2 Scope

This procedure applies to Apheresis Collection Centers qualified by Bristol Myers Squibb (BMS) to perform Adult MNC collections for BMS CAR T products in North America. The universal term "BMS" is used in this document to represent Juno, Celgene, and BMS.

1.3 Chain of Identity (COI)

1.3.1 Chain of Identity is the ability to link a patient to their autologous cellular material from the time of MNC collection through product administration. Specific controls and linkage elements are implemented at every process step to mitigate the risk of patient material mix-up and maintain a single COI. There is no standard analytical testing performed to identify a patient material mix-up. Failure to maintain COI could lead to detrimental product loss and/or serious health risk to the patient. The hazards associated with a potential autologous product mix-up necessitate stringent product and quality systems controls. The COI controls are summarized on the following page in Figure 1.

Note: *Chain of Identity steps will be emphasized with a COI verification icon and numbered purple arrow. See example below.*

Step 1 Sample Chain of Identity step

1.3.2 BMS autologous products are assigned a unique identifier called the JOIN that uniquely identifies a single apheresis treatment. The JOIN is associated with all records of a treatment and is printed on all labels affixed to patient material. To augment the JOIN and further reduce COI risks, labels used for apheresis and final product will also include the patient's identifiers or Subject Number for clinical trials, see Table 1.

Fig. 1 - COI Verification Process Steps

Pre-Collection Activities

1. Verify the JOIN, patient First Name, Last Name, Date of Birth and Subject Number (clinical collections only) on the MNC Label Set and Source Record* match.
2. Verify with the patient that the exact spelling of their First Name, Last Name, and Date of Birth on the MNC Bag Label is accurate.
3. Affix the verified MNC Bag Label to the front of the MNC Collection Bag.

Packaging the Collection

4. Prior to affixing the Shipping Address label, verify the JOIN on the MNC Bag Label, Shipping Address Label, and Collection Site Material Certificate of Conformance (CSMCC)** matches for the product being packaged. Affix the Shipping Address Label to the Shipper.
5. Verify the JOIN on MNC Bag Label and Shipping Address Label affixed to the Shipper matches before placing the MNC Product Bag in the shipper.
6. Verify the JOIN on the CSMCC** and Shipping Address Label affixed to the Shipper match. Place the CSMCC** on top of the cooling engine.
7. Verify the JOIN on the Shipping Address Label with the courier at time of pickup.

** The Cell Therapy 360 Apheresis Portal is the preferred Source Record. If the Portal is not available, use the Schedule Confirmation Form (SCF) as the Backup Source Record.*

*** Or the MNC Collection Procedure Record if the CSMCC is not available.*

1.4 Materials

1.4.1 BMS Supplied Materials:

- Back-up MNC Collection Set – For use if label generation in the Cell Therapy 360 Apheresis Portal is not available.

- Blank label stock for printing MNC Label Set from the Cell Therapy 360 Apheresis Portal.
- Cell Therapy 360 Apheresis Portal - used to document collection activities and print the MNC Label Set, Courier Waybills, and Collection Site Material Certificate of Conformance (CSMCC).
- Collection Site Material Certificate of Conformance (CSMCC) - Electronic record printed from Cell Therapy 360 Apheresis Portal after collection data has been submitted and prior to MNC collection packaging.
- MNC Label Set
  - Single page containing:
    a. (2) MNC Bag Labels
    b. (1) Shipping Address Label
- MNC Shipping Container Credo Cube – Shipping container for ide-cel products – will be delivered the day of collection.
  - Contents of the Credo Cube used for packaging the MNC product:
    a. Absorbent sheet
    b. BMS logo label
    c. Bubble wrap
    d. 'Do Not X-Ray' labels
    e. 'Exempt Human Specimen' label
    f. Specimen transport bag
    g. Temperature monitoring device
- MNC Shipping Container NanoCool – Shipping container for liso-cel products – may be stored on-site according to requirements detailed in Section 2.5.
  - Contents of the NanoCool used for packaging the MNC product:
    a. Absorbent sheet
    b. Bubble wrap
    c. Specimen transport bag
    d. Temperature monitoring device
- Schedule Confirmation Form – in the event the Cell Therapy 360 Apheresis Portal is not available

Note: *Check supplies often and always before a collection. Contact the Apheresis Operations Team to resupply: Apheresis@celltherapy360.com.*

1.4.2 Apheresis Collection Center Supplies:

- ACD-A anticoagulant
- 0.9% sodium chloride injection (saline) USP or medical grade equivalent
- Qualified scale for patient weight
- Shipping Tape (for packaging)
- BMS approved Apheresis Instruments and collection programs:
  - Includes the following:
    1. Spectra Optia Apheresis System
       a) MNC Collection Protocol
       b) CMNC Collection Protocol
    2. Amicus Separator
       a) MNC Collection Protocol
- Collection tubing set/kit appropriate for the apheresis instrument and collection program in use.

> ***Note:*** *No other collection instruments, programs, or kits are approved for use unless written notification has been provided by BMS.*

1.5 General Information

1.5.1 JOIN:

- The JOIN is the primary data element for BMS COI. It is a BMS generated unique identification code that is assigned to a patient's treatment and is associated to the patient's autologous blood product from the time of the leukapheresis scheduling through product administration.

1.5.2 Labeling Controls:

- In accordance with 21 CFR 1271, Apheresis Collection Centers must control all labels containing patient identifiers and/or JOIN information to ensure proper identification of the MNC Product and to prevent mix-ups. All unused patient specific collection labels supplied must be defaced or destroyed.
- If institutional labeling is required, centers must link institutional identification to the BMS issued JOIN so that the identifiers remain linked.

> ***Note:*** *When printing labels for more than one patient ensure the materials are segregated to prevent mix-up.*

1.5.3 Follow institutional policy for the following practices:

- Safe handling of blood products and personal protection.
- Aseptic technique.
- Patient evaluation and care
  - Assess each patient prior to collection following institutional policy to determine suitability to undergo the procedure.
- Peripheral Venous Access and Central Venous Access Device (CVAD) use and care.
- Operation and programming of the MNC collection device and parameters (e.g. Inlet/AC Ratio; Collect Flow Rate) unless otherwise indicated in this procedure.
- MNC collection except as specifically called out in this procedure.
- Biohazard waste management and disposal.
- Labeling as applicable for serological positive products.

1.5.4 Apheresis Information:

- ACD-A is the only anticoagulant approved for use during MNC Collection.
- No additional material should be added to the MNC Product other than what is specified in this procedure.
- Do not add additional ACD-A or other solutions to the MNC product.

> ***Note:*** *Plasma must be collected for liso-cel products, see Table 2. If using the Spectra Optia Apheresis System, program the machine to collect plasma directly into the product bag. If using the Amicus Separator, transfer plasma to the storage container prior to disconnecting the product from the device.*

- Post-collection sampling of the apheresis material is not required by BMS. If institutional procedures require sampling, follow procedures outlined in section 2.2.19.
- Package the MNC Product as soon as possible after completing the collection.
- Adverse events (AE) related to the MNC collection for BMS commercial products do not need to be reported to BMS.
- Adverse events (AE) related to the MNC collection for BMS clinical trials must be reported to BMS as per study protocol.

2. Procedures

2.1 Label Printing and Patient Identity Verification

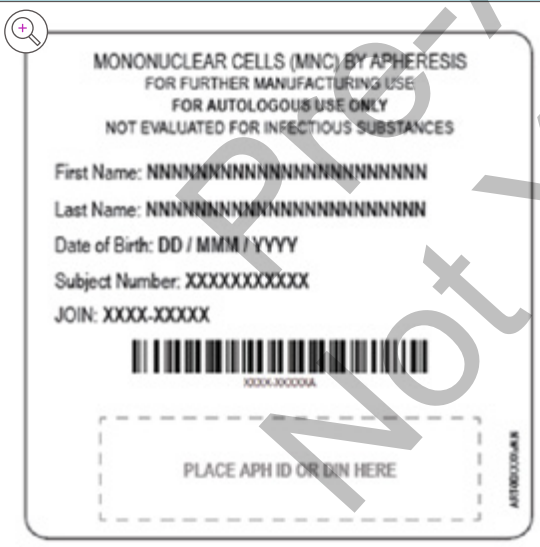
Collection specific documents are available to print 72 hours prior to the collection appointment.

If there is a discrepancy in identifiers at any time, do not proceed. Immediately contact the Scheduling & Cell Logistics team for further guidance.

> ***Note:*** *Example labels are found in Attachment B.*

2.1.1 Print the MNC Label Set and Courier Waybills directly from the Cell Therapy 360 Apheresis Portal as described in Table 4. The Portal generated MNC Bag Labels will be populated with the JOIN, patient's identifiers (first name, last name, and date of birth), and if applicable, Subject Number (clinical trial collections). See Figure 2 below.

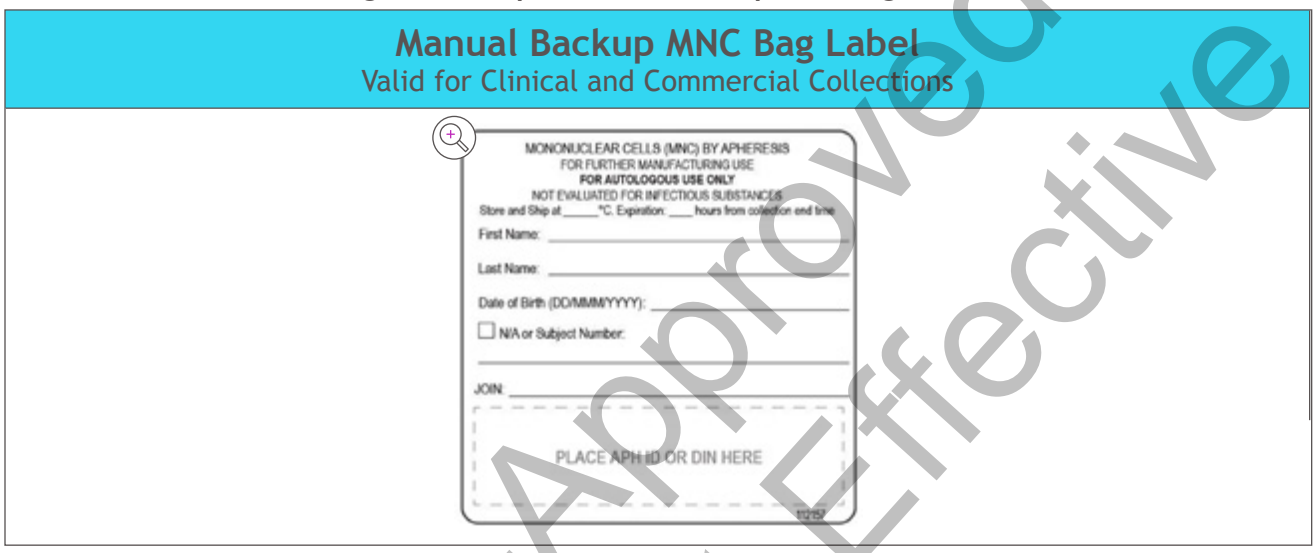
Fig. 2 - Example of the JOIN on Portal Generated MNC Bag Labels

Clinical Trial MNC Bag Label	Commercial MNC Bag Label
	

Note: *In the event that you cannot access the Cell Therapy 360 Apheresis Portal or cannot print labels, please contact Scheduling & Cell Logistics.*

2.1.2 If instructed, with indelible ink, complete the Manual Backup MNC Label using the Cell Therapy 360 Apheresis Portal or SCF as your BMS Source Record. Figure 3 below.

Fig. 3 - Example Manual Backup MNC Bag Label



2.1.3

Step 1 COI Verification: **Prior to the start of the collection**, verify the identifiers in Table 1 on the MNC Bag Label and Shipping Address Label exactly match the information in the Cell Therapy 360 Apheresis Portal (or the SCF if the Portal is not available).

Table 1 - MNC Label Set Verification: The table below dictates the identifiers to be confirmed on each BMS resource.

Verification	JOIN	Patient First Name	Patient Last Name	Patient Date of Birth	Subject Number (Clinical Trials Only)
Cell Therapy 360 Apheresis Portal (BMS Source Record)	✓	✓	✓	✓	✓
MNC Bag Label	✓	✓	✓	✓	✓
Shipping Address Label	✓				

2.1.4

Step 2 COI Verification: **Prior to the start of collection**, verify with the patient that the exact spelling of their First Name, Last Name, and Date of Birth on the MNC Bag Label is accurate. Patient identifiers on the MNC Bag Label must exactly match the verification method used with the patient. Acceptable verification methods include:

- Patient's government issued photo identification
- Patient's medical institution identification
- Verbal verification with the patient that is spelled aloud

Note: *BMS does not include middle names, initials, prefixes, or suffixes in patient names on labels or the Cell Therapy 360 Apheresis Portal*

2.1.5 Document the method of patient identity verification in the Cell Therapy 360 Apheresis Portal (Table 4) or on the MNC Collection Procedure Record if the Cell Therapy 360 Apheresis Portal is not available (Section 2.4).

2.1.6

Step 3 COI Verification: After patient verification has occurred, **but prior to the start of collection**, affix the verified MNC Bag Label onto the front of the MNC Collection Bag.

See Figure 4 on Page 13 for examples of acceptable MNC Bag Label placement.

- The BMS MNC Bag Label can be placed anywhere on the front of the MNC Collection Bag.
- If institutional labeling is required, it must be affixed to the bag within the boundaries of the base label. If the institutional label does not fit on the base label, it must then be affixed with a tie-tag.
- Do not place any labels on the back of the MNC Collection Bag. See example of acceptable labeling in Figure 4 on the following page.

Fig. 4 – MNC Collection Bag with Affixed MNC Bag Label and/or Institutional Label

A - Institutional barcode and BMS MNC bag label affixed to base label.
B - MNC bag label affixed to base label and institutional label attached with a tie tag.
C - Institutional label affixed to base label and BMS MNC bag label affixed to front of MNC collection bag.

2.2 Collection Procedure

2.2.1 Ensure the following steps have been completed prior to initiating collection:

- Access to the Cell Therapy 360 Apheresis Portal is available
- Print the MNC Label Set containing 2 MNC Bag Labels and 1 Shipping Address Label and Waybills
  - For Quick Courier, print 2 Waybills
  - For Marken Courier, print 4 Waybills
- Confirm shipping supplies are on hand, within expiry, and not damaged

> ***Note:*** *Contact Scheduling and Cell Logistics if any of these items are unavailable.*

2.2.2 Collections must occur in spaces that have been qualified and approved by BMS. Any changes to the collection or packaging location must be reported via the steps outlined in Section 5.2.

> ***Note:*** *When performing collections for more than one patient, ensure labels, collection documents, and shipping materials are segregated to prevent mix-up.*

2.2.3 Collection procedures should be completed prior to courier arrival for product pick-up.

> ***Note:*** *Courier pickup time can be changed in the Cell Therapy 360 Apheresis Portal or by calling Scheduling and Cell Logistics*

2.2.4 Whole Blood Process Volume (WBPV) is the run target for the MNC collection regardless of apheresis instrument used. The Absolute Lymphocyte Count (ALC) is used to determine collection targets. Targets are different depending on the product (Refer to Table 2 or the QRG in Section 3).

- ALC results drawn within 24 hours of collection start should be used to calculate targets.

2.2.5 The collection may be initiated prior to receipt of the ALC result.

- Program collection device to process highest WBPV.
- Adjust the run target when ALC results are received, if required.
- Contact Scheduling and Cell Logistics if the ALC will not be received in time to adjust the targets.

2.2.6 MNC Product volume and autologous plasma requirements differ by product.

- If the WBPV cannot be achieved, complete as much of the collection as possible.
- Contact Scheduling and Cell Logistics Team if WBPV targets cannot be achieved, prior to shipping the product.

Note: *Follow the WBPV as indicated in Table 2, over processing whole blood by >100mL should be avoided.*

Table 2 - Collection Requirements

Clinical Trial Collection Requirements				
Product Type	**If ALC ≥ 1k/µl**	**If ALC < 1k/µl**	**Autologous Plasma Volume**	**Total Product Volume Requirements**
lisocabtagene maraleucel (liso-cel / JCAR017)	WBPV Target = 7L	WBPV Target = 12L	150mL	≤ 450mL
CC-97540 CC-98633 CC-95266	Collection Target = **12L**		150mL	≤ 450mL

Product Type	**If ALC ≥ 0.5k/µl**	**If ALC < 0.5k/µl**	**Autologous Plasma Volume**	**Total Product Volume Requirements**
idecabtagene vicleucel (ide-cel / bb2121)	WBPV Target = **2 times** patient's TBV	WBPV Target = **3 times** patient's TBV	None	≥ 50mL

Table 2 - Collection Requirements (Continued)

Commercial Collection Requirements				
Product Type	**If ALC ≥ 1k/µl**	**If ALC < 1k/µl**	**Autologous Plasma Volume**	**Total Product Volume Requirements**
Breyanzi® (liso-cel)	WBPV Target = 7L	WBPV Target = 12L	150mL	≤ 450mL

Product Type	**If ALC ≥ 0.5k/µl**	**If ALC < 0.5k/µl**	**Autologous Plasma Volume**	**Total Product Volume Requirements**
ABECMA® (ide-cel)	WBPV Target = **2 times** patient's TBV	WBPV Target = **3 times** patient's TBV	None	≥ 50mL

Note: *Total product volume = MNC collect volume + autologous plasma volume.*

Table 3 - Collection Machine Specifications

Collection Device	Program Used	Monitoring Collection Specifics	End of Collection	Collection End Time	Plasma Collection (as applicable)
Spectra Optia	MNC or CMNC	**MNC Only:** Attempt to collect the contents of a partially full chamber	When "Run Target" Screen is displayed	Start of Rinseback	**CMNC Only:** Program machine to collect plasma directly into the product bag. **MNC Only:** Transfer plasma to the collect bag prior to disconnecting the product from the device.
Fenwal Amicus	MNC	Attempt to continue processing so the Final Mini-Cycle is completed	When "Perform Reinfusion" is displayed	Start of Reinfusion	Transfer plasma to the collect bag prior to disconnecting the product from the device.

2.2.7 Program WBPV to process based on the patient's ALC.

- Configure procedure parameters as defined in Table 2.
- Program remaining target values following institutional policy.

2.2.8 Program to collect plasma if required for product.

- **For Spectra Optia Apheresis System:** Program the machine to collect plasma directly into the product bag.
- **For Amicus Separator:** Transfer plasma to the storage container prior to disconnecting the product from the device.

2.2.9 Ensure COI steps 1-3 have been completed.

2.2.10 Connect the patient to the MNC collection tubing set.

2.2.11 Start the Collection.

- Record the start time of the collection in the Cell Therapy 360 Apheresis Portal (Table 4).

2.2.12 **Monitor the Collection**

- Follow institutional policy and manufacturer's equipment guide for collection performance and procedure optimization.

2.2.13 Ending the Collection (Table 3)

- Prior to ending the collection, ensure that the MNC Product volume requirements have been met (see Table 2 or QRG in Section 3).
- Follow the screen prompts to initiate Rinseback or Reinfusion.
- Record final run values and collection end time in the Cell Therapy 360 Apheresis Portal Table 4.

2.2.14 Disconnect the patient from the tubing set and provide care per institutional policy.

2.2.15 Disconnect the MNC Collection Bag from the tubing set.

- Strip the lines and position the clamps at the top of the collect/sampling lines.
- Seal the collect lines above the manifold leaving approximately 5 inches of tubing. Seal the sampling bulb assembly just above the manifold (See Figure 5).
- Leave a minimum of two seals on all lines.

2.2.16 Post-collection sampling of the MNC product is not required by BMS. If institutional procedures require sampling, the sample bulb(s) integrated with the collection set must be used following aseptic technique. If sampling the apheresis material, ensure the following:

- The product sample does not exceed 5mL
- The minimum BMS product volume must be met after sampling.
- Document the sample volume removed in the MNC Product Comment section of the Cell Therapy 360 Apheresis Portal.
- Do not provide product sample test results to BMS unless requested by BMS.

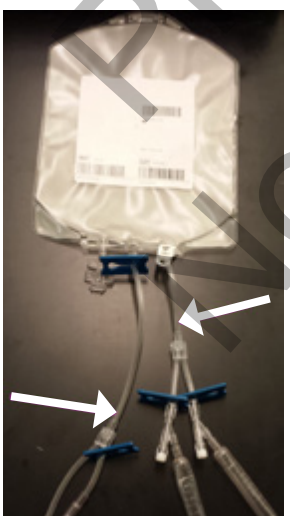
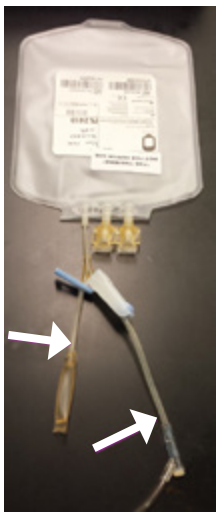
2.2.17 Release and remove any clamps.

2.2.18 Do not leave tubing flattened.

2.2.19 Immediately package the MNC Product for shipment using the product specific instructions in Section 2.5.

2.2.20 Dispose of the MNC Collection tubing set following institutional policy.

Fig. 5 - Seal line locations per Apheresis Kit

Spectra Optia Collection Set	Fenwal Amicus Apheresis Kit
	

2.3 Documenting the Collection

The Cell Therapy 360 Apheresis Portal is used to document collection related activities and patient-specific information. A summary of the Cell Therapy 360 Apheresis Portal parameters and troubleshooting information is located in Attachment E.

- When logging into the Cell Therapy 360 Apheresis Portal, note any announcements and review the resources tab.

> ***Note:*** *If the Cell Therapy 360 Apheresis Portal is not available, all collection information will be captured on the MNC Collection Procedure Record (Manual Backup Method). For instructions on how to document the collection using the MNC Procedure Record, see Section 2.4.*

Table 4 - Cell Therapy 360 Apheresis Portal Quick Guide

Please note: *The following images or screenshots are examples and may not represent current Portal interface*

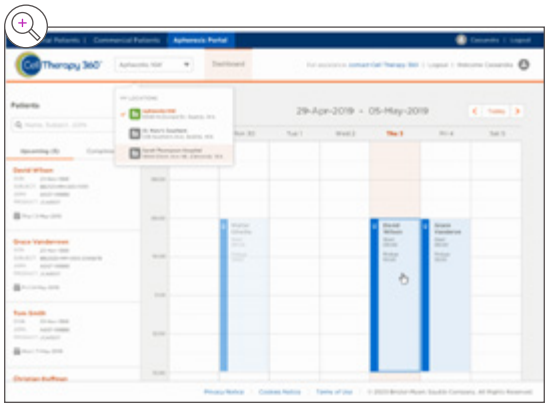
Step 1: Navigate to ct360.com

Log into the Cell Therapy 360 Apheresis Portal using the BMS provided username and password.

Username Format:
firstinitiallastname@ct360.com

If necessary, select the Apheresis Portal on the navigation bar in the top left corner.

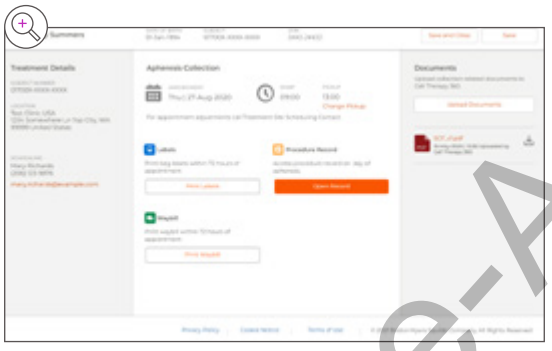
> ***Note:*** *Only one person should be logged into a treatment record at a time. If a hand off will take place during collection, save any details completed and log out. You will automatically be logged out after 15 minutes of inactivity.*

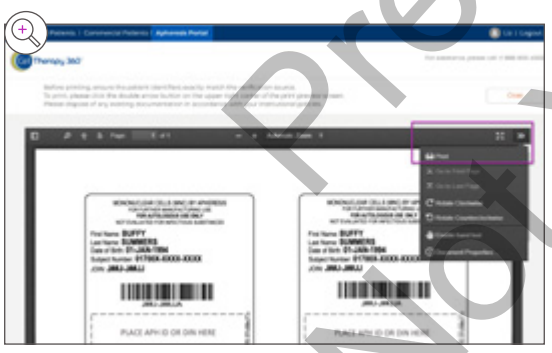


Step 2: Locate Patient

Navigate to the list of patients on the left-hand side or via the calendar. Click on the correct patient to open the collection record in the Patient Details page.

If you perform collections for more than one Apheresis Collection Center, select the correct Center from the dropdown list in the upper left-hand corner next to the "Dashboard" button.





Step 3: Generate Labels & Waybills

The "Print Labels" and "Print Waybill" buttons will be activated on the Patient Details page within 72 hours of the scheduled collection appointment.

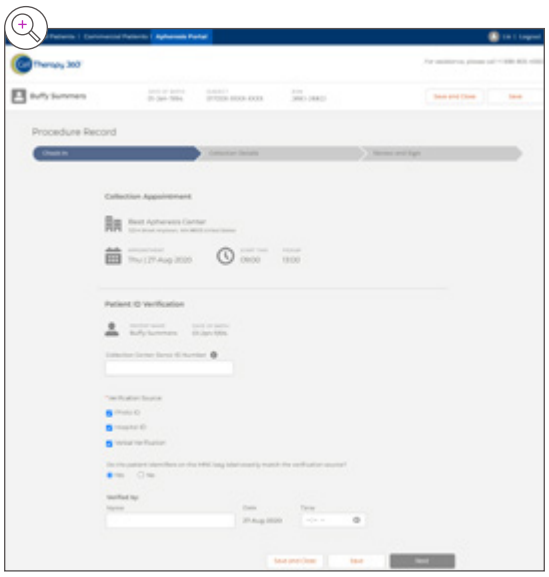
Once you have selected either of the buttons, click the double arrow button in the upper right corner of the print preview screen.

Use the BMS supplied blank label stock to print the MNC Label Set (includes (2) MNC Bag Labels and (1) Shipping Address Label). Waybills may be printed on normal printer paper.

Ensure the correct print settings are used so that the label content prints within the die cuts of the label stock.

Note: *You may reprint labels as needed. More labels may be printed if you require copies per institutional policies. Be sure to reconcile any unused labels.*

Step 1 COI Verification: **Prior to the start of collection**, verify the subject identifiers in Table 1 on the MNC Bag Label and Shipping Address Label exactly match the information in the Cell Therapy 360 Apheresis Portal (or the SCF if the Portal is not available).



Step 4: Open Procedure and Record Patient identity Verification

The Collection Procedure Record will be available the day of the appointment.

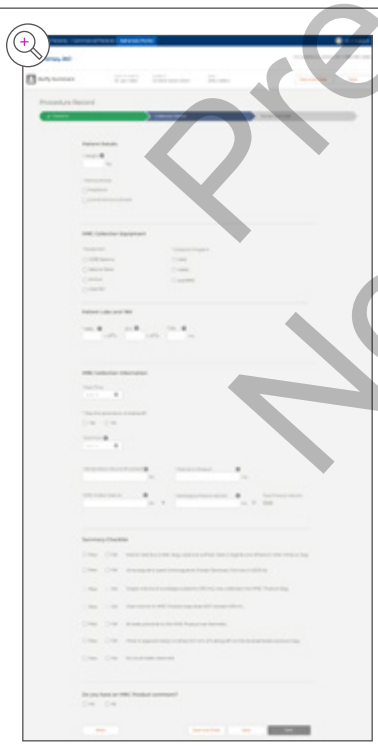
On the Check-In page, complete the Patient ID Verification section.

The Collection Center Donor ID Number is an optional field with a 16 character limit. This is the internal institutional number given to the specific product. If using a bar code scanner to complete this field remove any extra characters e.g. "=, +" if needed.

Confirm the patient's identifiers on the MNC bag label exactly match the verification source by selecting "yes".

In the final "Verified by" section, record the name of the person who completed COI Verification Step 2 and add the date/time the verification was completed.

Verification time must be before the collection start time.



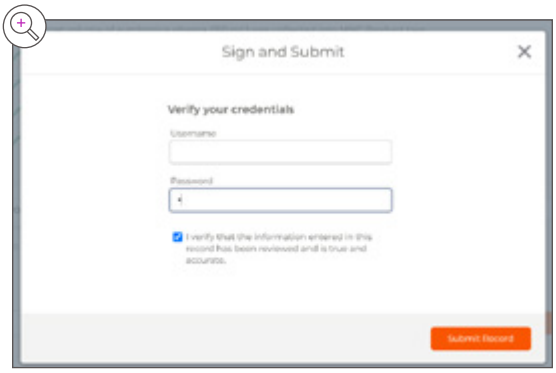
Step 5: Enter Collection Data

Enter collection details as prompted.
Weight field allows up to two decimals.

If any Summary Checklist item is marked "Fail", call Scheduling & Cell Logistics before proceeding with next steps.

> ***Note:*** *ALC should be entered in 1k/ul format (e.g. 0.9).*

Once completed, click "Next".

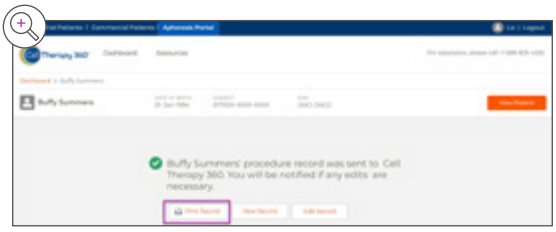


Step 6: Review Collection Data, Sign, & Submit

If any information needs to be amended, click on "Edit" and make necessary changes.

Once edits have been made, click "Save" then "Sign and Submit".

When prompted enter username and password and click "Submit Record".

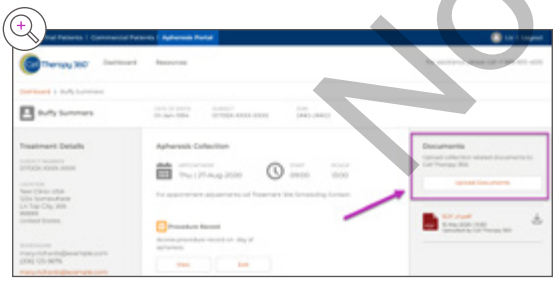


Step 7: Print CSMCC

After the record is submitted print a copy of the Collection Site Material Certificate of Conformance by selecting "Print Record".

Once the print preview screen appears, click on the double arrows in the top right to print the CSMCC.

Note: *A copy of the CSMCC must be shipped with the MNC product.*



Step 8: Uploading Supplemental Documents (if directed by BMS)

Return to the Dashboard by clicking "View Patient"

Supplemental documents may be uploaded by selecting the "Upload Documents" button from the Patient Details page.

Upload documents by dragging a document into the box or by selecting the file and selecting "Submit Documents".

Note: *The system will restrict users from uploading files other than the approved file types: *.doc, *.docx, *.pdf, *.png, *.jpeg, *.mp4, *.xls, *.xlsx, *.snote*

2.4 Manual Backup Method

- The MNC Collection Procedure Record is to be utilized only if directed by BMS.
- Instructions on how to complete the Manual Backup Method can be found on the back of the MNC Collection Procedure Record. Examples of the MNC Collection Procedure Records can be found in Attachment A.
- Complete each section of the procedure record completely and accurately.

> ***Note:*** *If any criteria are not met in the "MNC Collection Summary" section contact Scheduling & Cell Logistics immediately.*

- Sign and date the completed MNC Collection Procedure Record.
- Make a copy of the completed MNC Collection Procedure Record and transfer to packaging staff for COI verification and placement in shipper.
- Scan and upload the completed MNC Procedure Record (and any relevant files/forms) to your dedicated folder on Box.com.
  - If your Box.com account has already been set up, you should have access right away.
  - If you do not have a Box.com account previously set up, Scheduling & Cell Logistics will send you an invitation to Box.com via email. Once you've received the email invitation, click to "Accept Invite" and follow the subsequent instructions to create an account.

2.5 Packaging and Shipping the Apheresis Product

2.5.1 Follow steps outlined in Section 2 for collection specific details. Contact Scheduling & Cell Logistics at Scheduling@celltherapy360.com if any issues with the collection will cause a delay that will impact the courier pick up time by more than 30 minutes.

> ***Note:*** *When packaging for more than one patient ensure the materials are segregated to prevent mix-up.*

2.5.2 Confirm the Collection Site Material Certificate of Conformance has been printed or details have been captured on the MNC Collection Procedure Record if the Cell Therapy 360 Apheresis Portal is not available Section 2.4.

2.5.3 Closely follow the step-by-step instructions in Tables 5-7 to package the MNC product for shipment.

Table 5 - Designated Shippers per Product

Clinical Trial Collections		
Product Type	**Designated Shipper**	**Shipper Details**
liso-cel (JCAR017) **CC-97540** **CC-98633** **CC-95266**	NanoCool	stored on-site
ide-cel (bb2121)	CredoCube	delivered day of collection

Commercial Collections		
Product Type	**Designated Shipper**	**Shipper Details**
Breyanzi® **(liso-cel)**	NanoCool	stored on-site
ABECMA® **(ide-cel)**	CredoCube	delivered day of collection

2.5.4 See Table 6 for Packaging the NanoCool Shipper. See Table 7 for instructions for Packaging the Credo Cube Shipper. If you encounter any discrepancies with the processes as detailed, please contact Scheduling & Cell Logistics.

Table 6 - Packaging the NanoCool

	NanoCools are delivered to the site prior to the collection day and stored on-site. Retrieve the NanoCool shipping container and shipping supplies from the designated storage area. If the shipping container is expired or damaged (e.g., partially activated NanoCool lid, outer holes or tears, inner vacuum panels deformed, missing items, etc) discard and retrieve one from reserves stored on-site. If NanoCool is free of damages, proceed with COI step 4.
Step 4	COI Verification: Prior to affixing the Shipping Address Label, verify the JOIN on the MNC Bag Label, Shipping Address Label, and CSMCC* matches for the product being packaged. Affix the verified Shipping Address label to the side of the outer cardboard box. ** Or the MNC Collection Procedure Record if the CSMCC is not available.*
	Ensure that verified Shipping Address label has been affixed to the side of the outer cardboard box.

Open the corrugated sleeve of the MNC shipping container.

Carefully, remove the shipping container lid with the silver foil and place foil side down on a hard, flat, clean surface. The white actuator button should be pointing up.

Note: *The lid is the cooling engine. Take extra precautions to not drop the cooling engine. The silver foil side should feel gel-like to the touch.*

Verify that the NanoCool unit contains:

- Absorbent sheet
- Bubble wrap
- Specimen transport bag
- Temperature monitoring device (may be separate from the NanoCool unit upon delivery. If so, retrieve the temperature monitoring device and verify the device is within expiry).

If any of the above supplies are damaged or missing, retrieve another shipper from the reserves and notify BMS.

Insert the MNC Product into the specimen transport bag with the MNC Bag Label facing outward.

Note: *MNC Bag Label should be visible and not obstructed. The label should be facing the side of specimen transport bag without the biohazard print, so the label is legible while inside the bag.*

Insert the absorbent sheet into the specimen transport bag, ensuring not to obstruct the MNC Bag Label.

Verify that both the MNC product and absorbent sheets are placed inside the specimen transport bag and not in the outer document sleeve of the specimen transport bag.

Activate the temperature monitoring device by holding down the start (green) button for three (3) seconds, until you see the sunshine icon on the upper left corner of the LCD. Do not at any time touch the red stop button.

Remove the backing paper and adhere the temperature monitoring device to the exterior of the specimen transport bag.

Ensure that the temperature monitoring device does not obscure the MNC bag label.

Step 5

COI Verification: Verify the JOIN on the MNC Bag Label and Shipping Address Label affixed to the Shipper matches before placing the MNC Product Bag in the Shipper.

Pack the MNC Product in the center payload compartment with the MNC Bag Label facing up.

Place bubble wrap on top of the MNC Product to fill the void in the shipping container.

In one motion, press straight down on the actuator button. Only a moderate amount of force is necessary to depress the actuator.

Note: *Do not use a sharp object to press on the button.*

The NanoCool is activated once the NanoCool logo turns blue and the cooling engine is cool to the touch.

Note: *Do not press the button until ready to package the MNC Product.*

Align the cooling engine lid with the shipping container's internal cavity and press firmly and evenly to ensure a snug fit. Ensure there are no visible gaps between the cooling engine lid and the shipping container's internal cavity.

Step 6

COI Verification: Verify the JOIN on the CSMCC* and Shipping Address Label affixed to the Shipper matches for the product being packaged. Place the CSMCC* on top of the cooling engine.

** Or the MNC Collection Procedure Record if the CSMCC is not available.*

Ensure the CSMCC has been placed on top of the cooling engine.

Close the shipping container and insert the flaps. Tape the lid shut in the 3 locations marked “tape here” on the container.

Note: *Do not place any additional items into the shipping container unless detailed in this MNC Collection Procedure.*

Fold and insert signed copy(s) of the Courier Waybill into the adhesive document sleeve on the top of the shipping box.

Step 7 COI Verification: Verify the JOIN on the Shipping Address Label with the courier at time of pickup.

If Courier cannot produce JOIN and/or provides instructions not outlined in this collection procedure contact Scheduling and Cell Logistics.

Table 7 - Packaging in Credo Cube Shipper

	The courier will deliver a qualified, pre-cooled Credo Cube shipper on the day of collection. The Credo Cube maintains a temperature of 2-8°C. ***Note:*** *The shipper will arrive inside a corrugated cardboard box. Do NOT remove the shipper from the outer cardboard box.* In the event the Credo Cube has not yet been dropped off at your site by the time the collection has been completed, contact Scheduling & Cell Logistics immediately.
	Open the shipping container and remove the top silver insulation panel. Remove the top white refrigeration panel and inspect the inside of the shipping container for any leaks or obvious damage. • If the shipping container and/or supplies are free of damage, proceed. • If the shipping container and/or supplies are damaged, contact Scheduling & Cell Logistics immediately.
	Remove all items from the shipping container, **including the inner cardboard supply box** (if present). Verify that the container includes: • Absorbent sheet • BMS logo label • Bubble wrap • 'DO NOT X-RAY' labels • 'Exempt Human Specimen' label • Specimen transport bag • Temperature monitoring device ***Note:*** *Discard the inner cardboard supply box if one was provided.* *An example of the inner cardboard supply box can be seen in the step above.*

Label the outer cardboard corrugate the Credo arrived in with the following labels:

- 'DO NOT X-RAY'
- 'Exempt Human Specimen'
- BMS logo

Step 4

COI Verification: Prior to affixing the Shipping Address Label, verify the JOIN on the MNC Bag Label, Shipping Address Label, and CSMCC* matches for the product being packaged. Affix the verified Shipping Address label to the side of the outer cardboard box.

** Or the MNC Collection Procedure Record if using the manual backup procedure and the CSMCC is not available.*

Ensure that the verified Shipping Address Label has been affixed to the side of the outer cardboard box.

Place the MNC Product and absorbent sheet into the specimen transport bag with the MNC Bag label facing outward.

Note: *MNC Bag label should be visible and not obstructed. The label should be facing the side of specimen transport bag without the biohazard print, so the label is visible while inside the bag.*

Expel the air from the specimen transport bag, remove the adhesive, and seal the bag.

Activate the temperature monitoring device by holding down the start (green) button for three (3) seconds, until you see the sunshine icon on the upper left corner of the LCD. Do not at anytime touch the red stop button.

Remove the backing paper and adhere the temperature monitoring device to the exterior of the specimen transport bag.

Ensure that the temperature monitoring device does not obscure the MNC bag label.

Step 5

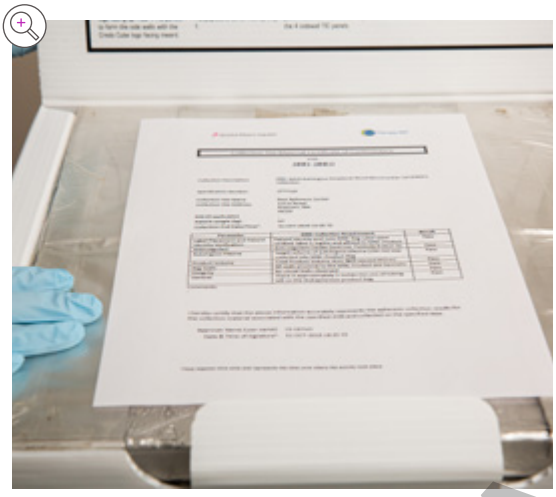
COI Verification: Verify the JOIN on the MNC Bag Label and Shipping Address Label affixed to the Shipper matches before placing the MNC Product Bag in the Shipper.

	Pack the MNC Product in the center payload compartment with the MNC Bag Label facing up. Place bubble wrap on top of the MNC Product to fill the void in the shipping container.
	Replace the white refrigeration panel on top of the packed transport bag and bubble wrap.
	Replace the silver insulation panel on top of the refrigeration panel.

Step 6

COI Verification: Verify the JOIN on the CSMCC* and Shipping Address Label affixed to the Shipper matches for the product being packaged. Place the CSMCC* on top of the cooling engine.

** Or the MNC Collection Procedure Record if the CSMCC is not available.*



Ensure the CSMCC has been placed on top of the credo cube cooling engine/silver insulation panel.

Close the shipping container.

Seal the top of the container with shipping tape.

Fold and insert signed copy(s) of the Courier Waybill into the adhesive document sleeve on the top of the shipping box.

Step 7

COI Verification: Verify the JOIN on the Shipping Address Label with the courier at time of pickup.

If Courier cannot produce JOIN and/or provides instructions not outlined in this collection procedure, contact Scheduling and Cell Logistics immediately.

3. Quick Reference Guide (1 of 2)

Attachment A - Quick Reference Guide: Collection and Packaging Requirements (1/2)

This QRG is a supplement to JSP-XXXXXX Adult MNC Collection Procedure - NorAm.

Prior to Collection

- Check supplies are on hand and not expired.
- Log into the Cell Therapy 360 Apheresis Portal (www.ct360.com) to print the BMS Label Set.
- Recommended to review patient's first name, last name, and date of birth against institutional record for accuracy and exact spelling.

COI checks
Prior to Collection

Step 1

Verify the JOIN, patient First Name, Last Name, Date of Birth, and Subject Number (clinical collections only) on MNC Bag Label Set and Source Record* Match.

** The Cell Therapy 360 Apheresis Portal is the preferred Source Record. If the Portal is not available, use the SCF as the Backup Source Record.*

Step 2

Verify with the patient that the exact spelling of their First Name, Last Name, and Date of Birth on the MNC Bag Label is accurate.

Step 3

Affix the verified MNC Bag Label to the front of the MNC Collection Bag.

NOTE: Do not proceed if any COI discrepancy occurs.
Immediately contact Scheduling & Cell Logistics for further guidance.

Collection Requirements

MNC Product	Collection Targets	
Breyanzi® liso-cel	✓	If **ALC** ≥ to 1k/uL: Process 7L whole blood
	✓	If **ALC** < 1k/uL: Process 12L whole blood
	✓	Plasma required: 150mL plasma collected into MNC bag
	✓	Total product volume must be less than or equal to 450 mL
CC-97540 CC-98633 CC-95266	✓	Collection Target = 12L
	✓	Plasma required: 150mL plasma collected into MNC bag
	✓	Total product volume must be less than or equal to 450mL
ABECMA® ide-cel	✓	If **ALC** ≥ .5k/uL: Process 2 times patient's TBV
	✓	If **ALC** < .5k/uL: Process 3 times patient's TBV
	✓	DO NOT ADD PLASMA
	✓	Total Product volume must be greater than or equal to 50mL

3. Quick Reference Guide (2 of 2)

Attachment A - Quick Reference Guide: Collection and Packaging Requirements (2/2)

Packaging

Materials needed for packaging:

- ☑ Labeled MNC Product
- ☑ Shipping Address Label
- ☑ Courier Waybills
- ☑ Collection Site Material Certificate of Conformance (CSMCC) or MNC Procedure Record
- ☑ Validated BMS Shipper*

***NOTE:** Do NOT remove Credo Cube from outer cardboard box it arrives in.

COI checks for Packaging

Step 4
Prior to affixing the Shipping Address label, verify the JOIN on the MNC Bag Label, Shipping Address Label, and CSMCC** matches for the product being packaged. Affix the Shipping Address Label to the Shipper.

Step 5
Verify the JOIN on the MNC Bag Label and Shipping Address Label affixed to the Shipper matches before placing MNC Product Bag in the Shipper.

Step 6
Verify the JOIN on the CSMCC** and Shipping Address Label affixed to the Shipper match. Place the CSMCC** on top of the cooling engine.

Step 7
Verify the JOIN on the Shipping Address Label with the courier at time of pickup.

***Or the MNC Collection Procedure Record if the CSMCC is not available.*

Includes:
- Absorbent sheet
- Bubble wrap
- Specimen transport bag
- Temperature monitoring device

Call SCLT for inventory issues

Color of cardboard box may vary

Includes:
- Absorbent sheet
- Bubble wrap
- Specimen transport bag
- Temperature montoring device
- Labels: BMS Logo; 'Exempt Human Specimen'; 'Do Not X-Ray'

NOTE: Do not proceed if any COI discrepancy occurs.
Immediately contact Scheduling & Cell Logistics for further guidance.

Resources

- CT360 Apheresis Portal: **www.ct360.com** - For printing of BMS documents and collection data entry.
- Rise Training Site: **www.ct360.rise.com** - For self-led training on Apheresis Collection Training.
- Box.com: **www.box.com** - For uploading paper MNC Collection Procedure Record if Portal is unavailable.

4. BMS Online Training Platform

4.1 ct360.Rise.com

4.1.1 Online training site https://ct360.rise.com, contains this MNC Collection Procedure, and other relevant training materials.

> ***Note:*** *Username (institutional email address) and password are required to access this site. Access will be granted prior to Apheresis Collection training.*

5. Deviations and Change Management

5.1 If a deviation to this protocol occurs, report via steps 5.1.1-5.1.3

5.1.1 Any deviation that has the potential to impact the quality, safety, or testing of the MNC product must be reported to Scheduling & Cell Logistics. Collection Sites must notify Scheduling & Cell Logistics of any relevant deviation as soon as possible, but within 24 hours of discovery, to help ensure the collection is not negatively impacted by the deviation. Examples include but are not limited to: no plasma added to the Breyanzi®/liso-cel MNC collection, MNC product voume is outside specification, or patient ID discrepancy was discovered.

- If the deviation is discovered on the day of the MNC collection appointment (or within the following 24 hours) call the Scheduling & Cell Logistics line immediately at: +1 (888) 805-4555 Option #2, Option #1 (U.S.) or +1 (855) 999-0170 (Canada).
- If the deviation is discovered later (e.g. during review of records), report it by email to Scheduling & Cell Logistics at Scheduling@celltherapy360.com.

5.1.2 When reporting a deviation provide the following information:

- Date of MNC collection
- Subject Number ***(if applicable)***
- JOIN
- Description of the deviation

5.1.3 The description of the deviation should include the following:

- Full name of person reporting the deviation
- Expected outcomes as if no deviation had occurred
- Actual outcome with occurrence of the deviation
- Immediate corrective action(s) taken to mitigate risk
- Assessment of impacts to the MNC collection product, if applicable

5.2 Changes to the qualified collection or packaging space/location must be reported via steps 5.2.1-5.2.2 below per the Quality Agreement

5.2.1 Notify Scheduling & Cell Logistics in writing minimally 30 days prior to the change. Email details of the change to Scheduling@celltherapy360.com and apheresis@celltherapy360.com. The description of the change should include the following:

- Full name of person reporting the change
- Full description of the proposed change including current qualified location/address and new proposed location/address
- Potential impact of the change on the collection services and impact to this collection
- Proposed implementation date of the change

5.2.2 BMS may request additional information or take additional steps to assess the impact of the change prior to approval.

6. Definitions

6.1 Absolute Lymphocyte Count (ALC) – Total count of lymphocytes obtained from a Complete Blood Count (CBC) with differential, measured in cells $x10^9$ per Liter (L) (Units: $x10^9$/L= K/µL= $x10^3$/µL).

- ALC may be calculated by multiplying the White Blood Count (WBC) by the percent lymphocytes. (Example: if WBC = 4.5 $x10^9$/L and percent lymphocytes = 20%, then ALC = 4.5 $x10^9$/L x 0.20 = 0.9 $x10^9$/L)
- See Table 2 or the QRG in Section 3 for ALC collection parameters and processing targets.

6.2 Amicus Separator ("Amicus") – An automated blood cell separator manufactured by Fenwal, Inc. indicated for the collection of blood components and mononuclear cells. The Amicus Separator system is approved by the FDA and BMS to perform MNC collections.

6.3 Anticoagulant Citrate Dextrose, Formula A (ACD-A) – A chemical substance added to blood that inhibits clotting by binding ionized calcium; for Formula A, each 100mL of solution contains 2.2g sodium citrate hydrous, 730mg citric acid anhydrous and 2.45g dextrose hydrous; also known as sodium citrate.

6.4 Autologous Plasma – Plasma collected from the patient during the MNC collection and added to the MNC Collection Bag.

6.5 Cell Therapy 360 Apheresis Portal – A secure web-based system that allows Apheresis Collection Centers to access collection and patient related information for patients participating in BMS clinical trials or prescribed BMS commercial CAR T products. By accessing the Portal, Apheresis Collection Centers may view past or upcoming apheresis collections, view patient specific details, generate collection specific documents, document patient identity verification, enter collection specific data and print a Collection Site Material Certificate of Conformance (CSMCC) for inclusion in the apheresis shipper. This Portal is considered a source document used from the time of the MNC collection throughout the manufacturing process to verify and ensure Chain of Identity elements are assigned and maintained.

6.6 Chain of Identity (COI) – The ability to link a patient's autologous cellular material from the time of MNC collection through product administration. Specific controls and linkage elements are implemented at every process step to mitigate the risk of patient material mix-up and maintain a single Chain of Identity. Refer to Section 1.3 for more information on Chain of Identity.

6.7 Change Management – Changes to the collection space or site location, BMS specific collection procedures or records, or practices related to Chain of Identity verification must be approved by BMS before implementation. Report the change via the steps outlined in Section 5.

6.8 Collection Start Time – The time when the MNC collection procedure is started. The start time for each apheresis device is defined in Table 8 below.

6.9 Collection End Time – The time at the completion of the MNC collection when no further MNCs are collected. The end time for each apheresis device is defined in Table 8 below.

Table 8 – Collection Start Time/Collection End Time by Device

Apheresis Device	Collection Start Time	Collection End Time
	When operator selects:	
Spectra Optia Apheresis System	Start Run	Start of Rinseback
Amicus Separator	Begin Collection	Start of Reinfusion

6.10 Collection Site Material Certificate of Conformance (CSMCC) – Electronic record generated by the Cell Therapy 360 Apheresis Portal which captures the JOIN and collection data upon submission. This document includes information that will be used to receive the MNC collection at the manufacturing facility and to manufacture the drug product.

6.11 Courier Waybill – Courier Waybills are printed directly from the Cell Therapy 360 Apheresis Portal. The Courier Waybill contains the JOIN and is used to maintain COI.

6.12 Credo Cube Shipper – Validated shipper provided by BMS used to ship ide-cel. products. Credo Cube Shippers are delivered on the day of collection by a courier.

6.13 JOIN – The JOIN is the primary data element for BMS COI. It is a BMS generated unique identification code that is assigned to a patient's treatment and is associated to the patient's autologous blood product from the time of the leukapheresis scheduling through product administration. The JOIN is a 10-character pseudo-random data element consisting of 4 alphanumeric characters, a hyphen, and 5 alphanumeric characters. A JOIN can be composed entirely of numbers, letters, or any combination thereof. To augment the JOIN and further reduce COI risks, labels used for apheresis and final product will also include patient identifiers, as depicted in Figure 6.

Fig. 6 – Example JOIN on MNC Bag Label

6.14 MNC Bag Label – Label that is affixed to the front of the MNC Collection Bag after patient identity verification is performed. The identifiers are verified with the patient prior to the collection. This is the first identification step of the manufacturing process to associate the product with its JOIN. Labels are printed directly from the Cell Therapy 360 Apheresis Portal prior to collection.

6.15 MNC Collection Bag – The bag attached to the MNC procedure tubing kit where collected MNCs are stored. Specific instrument terms used for this volume are as follows:

- Spectra Optia Apheresis System – Collection Bag
- Amicus Separator – Storage Container

6.16 MNC Collection Procedure Record – BMS record used to document the patient identifiers, JOIN, and collection data in the event the Cell Therapy 360 Apheresis Portal is not available. This form includes information that will be used to receive the MNC collection at the manufacturing facility and to manufacture the drug product. Examples of the MNC Collection Procedure Records can be found in Attachment A.

6.17 MNC Product – Final collection configuration consisting of ACD-A, collect volume, and autologous plasma, if applicable, in the MNC Collection Bag (Reference Table 2 or the QRG in Section 3). The product must be sealed using heat seals or metal clips and packaged according to collection requirements.

6.18 NanoCool Shipping Container - Validated shipper provided by BMS used to ship liso-cel products. A case of 2-4 NanoCools is shipped to site ahead of collection and replenished as needed.

6.19 Patient Identifiers – Personal identifying information (e.g. name and date of birth) by which an individual can be recognized. Patient identifiers are used with the JOIN to ensure Chain of Identity is maintained.

6.20 Patient Identity Verification – The act of confirming patient identity. This activity is performed by ensuring the patient's identifiers and JOIN on the MNC Bag Label exactly match The Cell Therapy 360 Apheresis Portal or the Schedule Confirmation Form (if the Portal is not available). Upon patient arrival, this activity is performed by confirming the spelling of the patient identifiers on the MNC Bag Label exactly match their identification (e.g. Driver's License or Medical Institution Identification) or by verbally confirming the label content and spelling directly with the patient.

6.21 Schedule Confirmation Form (SCF) – This BMS issued form is considered a source document in the event the Cell Therapy 360 Apheresis Portal is not available. A copy of the SCF can be found in the Document Section of the Patient Details page in the Portal. The form contains collection specific identifiers such as: product type, patient's first and last name, date of birth, JOIN, and scheduled collection date. It is used from the time of the MNC collection throughout the manufacturing process to verify and ensure chain of identity elements are assigned and maintained. See Attachment C for an example SCF.

6.22 Shipping Address Label – Label that is affixed to the exterior of the MNC shipping container. This label contains at a minimum the JOIN and delivery address of the manufacturing facility.

6.23 Source Record – Authoritative data source for given data elements or piece of information containing patient identifiers, patient number, and JOIN. BMS source records are the Cell Therapy 360 Apheresis Portal or the SCF (if the Portal is not available).

6.24 Spectra Optia Apheresis System ("Spectra Optia") – Automatic blood component separator manufactured by TerumoBCT that uses centrifugation and optical detection (automated interface management system) to perform apheresis procedures. The Spectra Optia Apheresis System may be programmed to perform MNC collections using either MNC or Continuous MNC (CMNC) collection protocols, which are both approved by the FDA and BMS to perform MNC collections for their clinical and commercial CAR T products.

- **MNC Collection** – Cells are collected in cycles using plasma to flush them from a collection chamber into the MNC Collection Bag.
- **Continuous MNC (CMNC) Collection** – Cells are collected in cycles using plasma to flush them from a collection chamber into the MNC Collection Bag. Cells are separated and collected continuously (no cycles).

6.25 Subject Number – Clinical trial specific numbering scheme with elements of the clinical protocol, clinical site ID and sequential subject numbering.

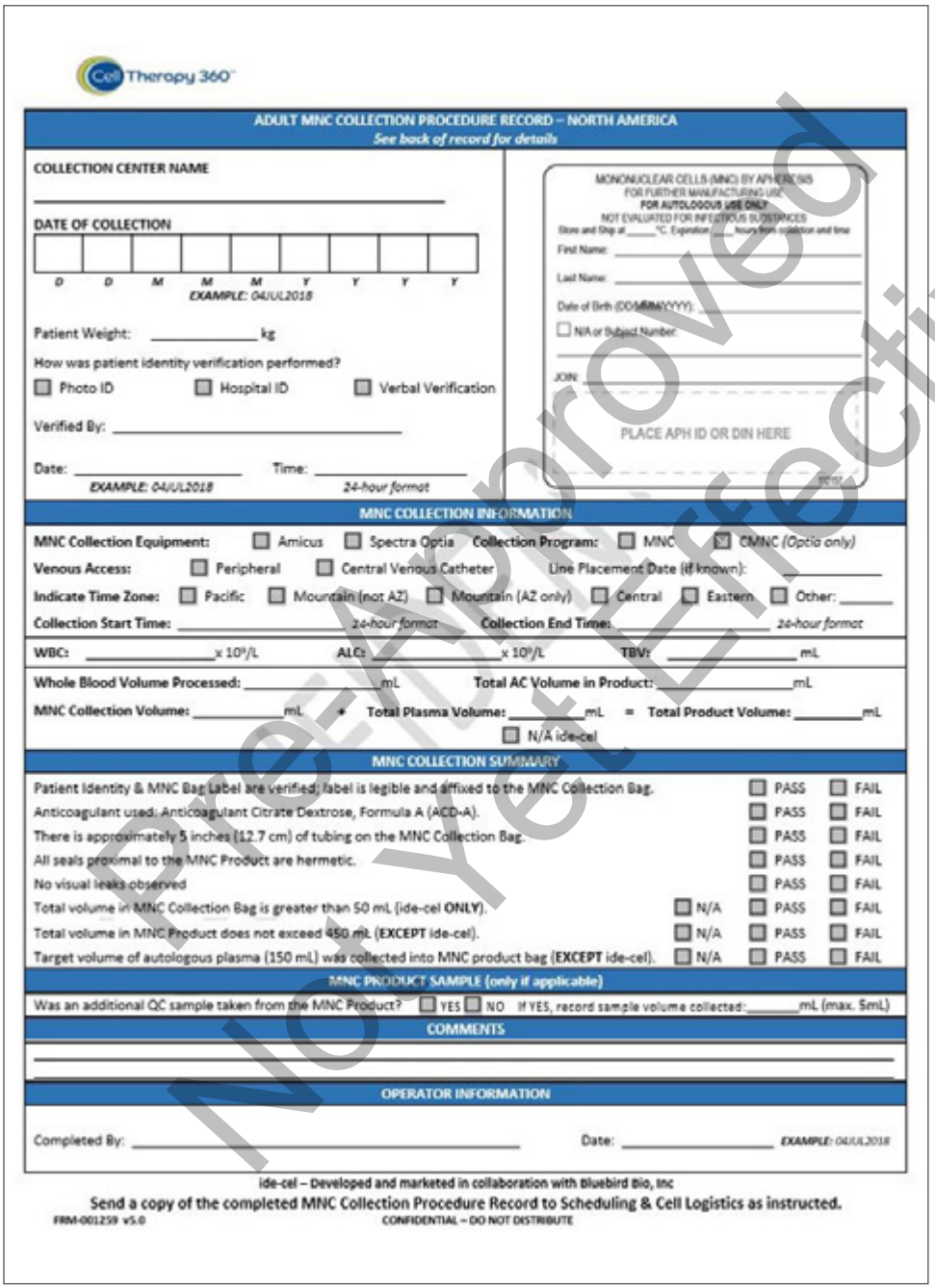
6.26 Total Blood Volume (TBV) – The volume of the patient's circulating blood within their body including plasma and all cellular components. TBV is calculated by the apheresis instrument using the patient's sex, height and weight (Nadler's equation).

6.27 Whole Blood Processed Volume (WBPV) – The volume of whole blood that travels over the collect or inlet pump during the collection procedure. Specific instrument terms used for this volume are as follows:

- Amicus Separator – Whole Blood Processed Volume.
  - This volume includes anticoagulant
- Spectra Optia Apheresis System – Whole Blood Processed Volume.
  - This volume **does not include** anticoagulant.

Attachment A

Example MNC Collection Procedure Record & Instructions (1 of 2)



Cell Therapy 360

ADULT MNC COLLECTION PROCEDURE RECORD – NORTH AMERICA
See back of record for details

COLLECTION CENTER NAME

_____

DATE OF COLLECTION

D	D	M	M	M	Y	Y	Y	Y

EXAMPLE: 04/JUL2018

MONONUCLEAR CELLS (MNC) BY APHERESIS
FOR FURTHER MANUFACTURING USE
FOR AUTOLOGOUS USE ONLY
NOT EVALUATED FOR INFECTIOUS SUBSTANCES
Store and Ship at ____°C. Expiration ____ hours from collection and time
First Name: _____
Last Name: _____
Date of Birth (DD/MM/YYYY): _____
☐ N/A or Subject Number: _____
JOIN _____
PLACE APH ID OR DIN HERE

Patient Weight: _____ kg

How was patient identity verification performed?
☐ Photo ID ☐ Hospital ID ☐ Verbal Verification

Verified By: _____

Date: _____ Time: _____
EXAMPLE: 04/JUL2018 *24-hour format*

MNC COLLECTION INFORMATION

MNC Collection Equipment: ☐ Amicus ☐ Spectra Optia **Collection Program:** ☐ MNC ☐ CMNC *(Optia only)*
Venous Access: ☐ Peripheral ☐ Central Venous Catheter Line Placement Date (if known): _____
Indicate Time Zone: ☐ Pacific ☐ Mountain (not AZ) ☐ Mountain (AZ only) ☐ Central ☐ Eastern ☐ Other: _____
Collection Start Time: _____ *24-hour format* **Collection End Time:** _____ *24-hour format*

WBC: _____ x 10^9/L **ALC:** _____ x 10^9/L **TBV:** _____ mL

Whole Blood Volume Processed: _____ mL **Total AC Volume in Product:** _____ mL

MNC Collection Volume: _____ mL + **Total Plasma Volume:** _____ mL = **Total Product Volume:** _____ mL
☐ N/A ide-cel

MNC COLLECTION SUMMARY

Patient Identity & MNC Bag Label are verified; label is legible and affixed to the MNC Collection Bag.		☐ PASS	☐ FAIL
Anticoagulant used: Anticoagulant Citrate Dextrose, Formula A (ACD-A).		☐ PASS	☐ FAIL
There is approximately 5 inches (12.7 cm) of tubing on the MNC Collection Bag.		☐ PASS	☐ FAIL
All seals proximal to the MNC Product are hermetic.		☐ PASS	☐ FAIL
No visual leaks observed		☐ PASS	☐ FAIL
Total volume in MNC Collection Bag is greater than 50 mL (ide-cel **ONLY**).	☐ N/A	☐ PASS	☐ FAIL
Total volume in MNC Product does not exceed 450 mL (**EXCEPT** ide-cel).	☐ N/A	☐ PASS	☐ FAIL
Target volume of autologous plasma (150 mL) was collected into MNC product bag (**EXCEPT** ide-cel).	☐ N/A	☐ PASS	☐ FAIL

MNC PRODUCT SAMPLE (only if applicable)

Was an additional QC sample taken from the MNC Product? ☐ YES ☐ NO If YES, record sample volume collected: _____ mL (max. 5mL)

COMMENTS

_____

_____

OPERATOR INFORMATION

Completed By: _____ Date: _____ *EXAMPLE: 04/JUL2018*

ide-cel – Developed and marketed in collaboration with Bluebird Bio, Inc

Send a copy of the completed MNC Collection Procedure Record to Scheduling & Cell Logistics as instructed.

FRM-001259 v5.0 CONFIDENTIAL – DO NOT DISTRIBUTE

Attachment A

Example MNC Collection Procedure Record & Instructions (2 of 2)

Cell Therapy 360

INSTRUCTIONS FOR COMPLETING THE MNC COLLECTION PROCEDURE RECORD

Collection Center Name: *Document the name of your institution listed in the Cell Therapy 360 Apheresis Portal or written on the Schedule Confirmation Form (SCF).*
Date of Collection: *Document in the DDMMMYYYY format, where "MMM" is the 3-letter abbreviation for the month (e.g. JAN, APR, JUL, OCT, etc.).*
Patient's Weight: *Obtained within 24 hours of collection.*
Donor Identification Number: *If applicable, the unique collection center donor identification number may be recorded.*
How was patient identity verification performed? *Verify the spelling of the patient's first and last names and date of birth and indicate the verification source(s) used (Photo ID, Hospital ID and/or Verbal Verification), prior to labeling the MNC Collection Bag. Patient identifiers on the BMS MNC Bag Label must exactly match the information provided by the patient at the time of verification.*
Verified By: *Name of the staff member who verified patient/subject identity.*
Date: *Date that identity verification took place using DDMMMYYYY format (e.g. 04JUL2018)*
Time: *Time that identity verification took place using 24-hour format (e.g. 0700, 1315, 1500). Verification time should be prior to the collection start time.*
Mononuclear Cell (MNC) Bag Label Content: *The following information can be transcribed directly from Cell Therapy 360 Apheresis Portal or Schedule Confirmation Form or a Leukapheresis Bag Label can be affixed to the form in lieu of transcribing the following:*
- **First Name:** *Patient's First Name*
- **Last Name:** *Patient's Last Name*
- **Date of Birth:** *Patient's Date of Birth (DDMMMYYYY format)*
- **Subject Number:** *Clinical Subject Number, not applicable for Commercial CAR T patients*
- **JOIN:** *Leukapheresis Identification Number (unique product identifier)*

MNC COLLECTION INFORMATION

MNC Collection Equipment: *Check device used for MNC Collection - Spectra Optia or Amicus*
Collection Program: *Check program used for MNC Collection. Should be MNC unless using Continuous MNC (CMNC) on Spectra Optia*
Venous Access: *Check venous access type – Peripheral or Central Venous Catheter*
Patient Labs: *Document TBV calculated by collection device.* ***(Units: x10⁹/L= K/µL= x10³/ µL)***
- **WBC:** *White Blood Cell Count x 10⁹/Liter (L)* **ALC:** *Absolute Lymphocyte Count x 10⁹/L*
- **TBV:** *Total Blood Volume in mL*

Collection Start Time: *Documented in 24-hour format. Clock time when the collection procedure is started as defined in the MNC Collection Protocol. Collection Start Time should be after verification time.*
Collection End Time: *Documented in 24-hour format. Clock time at the completion of leukapheresis collection. This time is the* ***INITIATION*** *of rinseback or reinfusion.*
Indicate Time Zone: *Check the appropriate time zone for the collection center location (if "Other" is checked, write in time zone).*
Whole Blood Volume Processed: *Collection device should be programmed to target based on ALC result*
- *ide-cel products 2x or 3x patient's Total Blood Volume*
- *lisa-cel products 7 or 12 Liters*
- *NEX T/ GPRC5D/HPV eTCR/ROR-1 products 12 Liters*

Total AC Volume in Product: *Total anticoagulant (AC) volume in the MNC Collection Bag- ACD-A only.*
MNC Collection Volume: *Volume of collected MNC product. This value includes AC but does not include autologous plasma.*
Autologous Plasma Volume: *Plasma collected during the MNC collection and added to the MNC Collection Bag. This value includes AC (applicable to all products* ***EXCEPT*** *ide-cel).*
Total Product Volume: *Content in the MNC Collection Bag at the end of the procedure: Sum of the MNC collection, AC volume, and autologous plasma if applicable.*

MNC COLLECTION SUMMARY

Checking "Pass" indicates compliance with the requirements listed in this section.
NOTE: If the collection was not completed or all requirements were not met, immediately contact Scheduling & Cell Logistics at: 1-888-805-4555, Option #2 (US) or 1-855-999-0170, Option #1 (Canada) or email Scheduling@CellTherapy360.com.

MNC PRODUCT SAMPLE ***(only if applicable)***

Check "YES" ***only*** *if an additional QC sample was taken from the MNC Product; list the sample volume in mL. This volume is not subtracted from the MNC Collection Volume value.*
NOTE: Do not exceed maximum sample volume (5mL).

COMMENTS

Add any relevant comments regarding the MNC Product (not required).

ide-cel – Developed and marketed in collaboration with Bluebird Bio, Inc

Send a copy of the completed MNC Collection Procedure Record to Scheduling & Cell Logistics as instructed.

FRM-001259 v5.0 CONFIDENTIAL – DO NOT DISTRIBUTE

Attachment B-1

Example MNC Label Sets (1 of 3)

Apheresis Portal Generated MNC Label Set - Clinical Trials

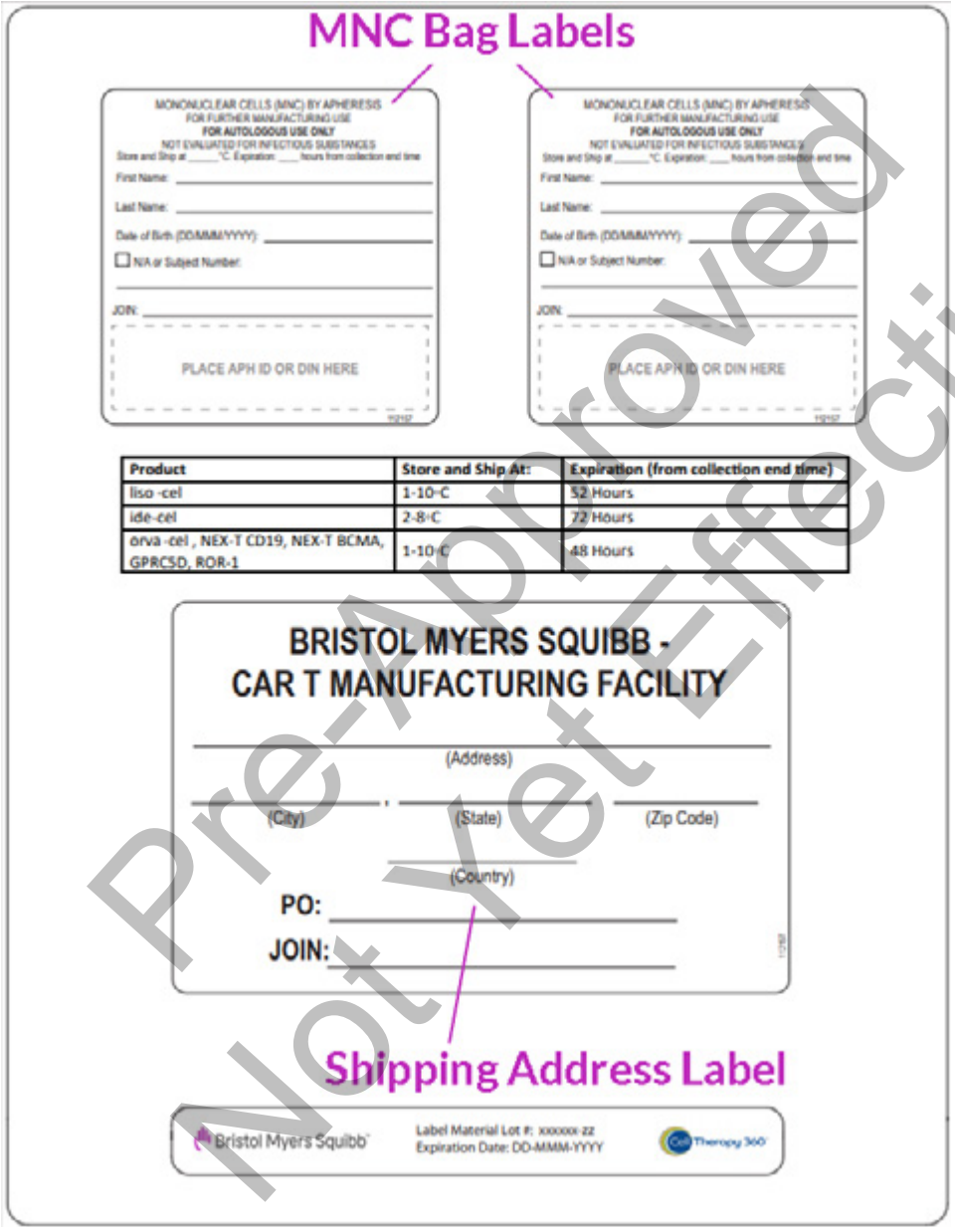
Attachment B-2

Example MNC Label Sets (2 of 3)

Apheresis Portal Generated MNC Label Set - Commercial Collections

Attachment B-3

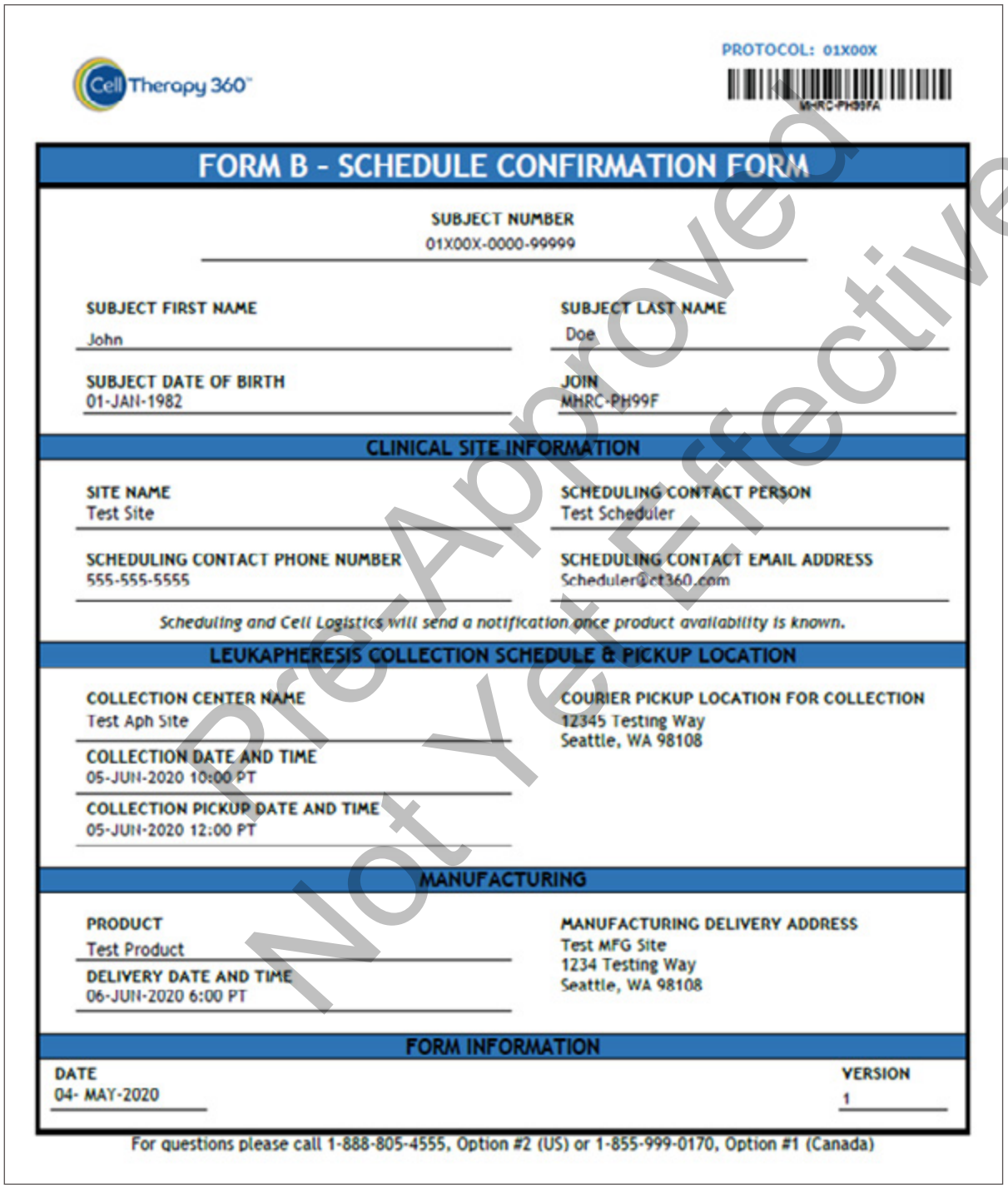
Example MNC Label Sets (3 of 3)



Manual Backup MNC Label Set - Clinical Trial & Commercial Collections

Attachment C

Example Schedule Confirmation Form (SCF)



Cell Therapy 360™

PROTOCOL: 01X00X

FORM B - SCHEDULE CONFIRMATION FORM

SUBJECT NUMBER
01X00X-0000-99999

SUBJECT FIRST NAME
John

SUBJECT LAST NAME
Doe

SUBJECT DATE OF BIRTH
01-JAN-1982

JOIN
MHRC-PH99F

CLINICAL SITE INFORMATION

SITE NAME
Test Site

SCHEDULING CONTACT PERSON
Test Scheduler

SCHEDULING CONTACT PHONE NUMBER
555-555-5555

SCHEDULING CONTACT EMAIL ADDRESS
Scheduler@ct360.com

Scheduling and Cell Logistics will send a notification once product availability is known.

LEUKAPHERESIS COLLECTION SCHEDULE & PICKUP LOCATION

COLLECTION CENTER NAME
Test Aph Site

COLLECTION DATE AND TIME
05-JUN-2020 10:00 PT

COLLECTION PICKUP DATE AND TIME
05-JUN-2020 12:00 PT

COURIER PICKUP LOCATION FOR COLLECTION
12345 Testing Way
Seattle, WA 98108

MANUFACTURING

PRODUCT
Test Product

DELIVERY DATE AND TIME
06-JUN-2020 6:00 PT

MANUFACTURING DELIVERY ADDRESS
Test MFG Site
1234 Testing Way
Seattle, WA 98108

FORM INFORMATION

DATE
04- MAY-2020

VERSION
1

For questions please call 1-888-805-4555, Option #2 (US) or 1-855-999-0170, Option #1 (Canada)

Attachment D

Example Collection Site Material Certificate of Conformance (CSMCC)

Bristol Myers Squibb™ Cell Therapy 360™

Collection Site Material Certificate of Conformance

JOIN:

E##E-E##EE

E##E-E##EEA

Collection Description: Adult Autologous Peripheral Blood Mononuclear Cell (PBMC) Collection

Specification Number: SPEC-liso-cel

Collection Site Name: Best Apheresis Center

Collection Site Address: 123 A Street
Anytown, WA
98103

APH ID/DIN (if applicable): -

Patient weight (kg): 60

Collection End Date/Time[1]: 04-SEP-2020 12:05 TZ

Parameter	MNC Collection Requirement	Result
Label Placement and Patient Identity Verification	Patient Identity & MNC Bag Label are verified; label is legible and affixed to MNC Product bag.	Pass
Anticoagulant	Anticoagulant used: Anticoagulant Citrate Dextrose, Formula A (ACD-A)	Pass
Autologous Plasma	Target volume of autologous plasma (150 mL) was collected into MNC Product bag.	Pass
Product Volume	Total volume in the MNC Product bag does **NOT** exceed 450 mL	Pass
Bag Seals	All seals proximal to the MNC Product are hermetic.	Pass
Integrity	No visual leaks observed.	Pass
General	There is approximately 5 inches (12.7 cm) of tubing left on the leukapheresis product bag.	Pass

Comments:
-

I hereby certify that the above information accurately represents the apheresis collection results for the collection material associated with the specified JOIN and collected on the specified date.

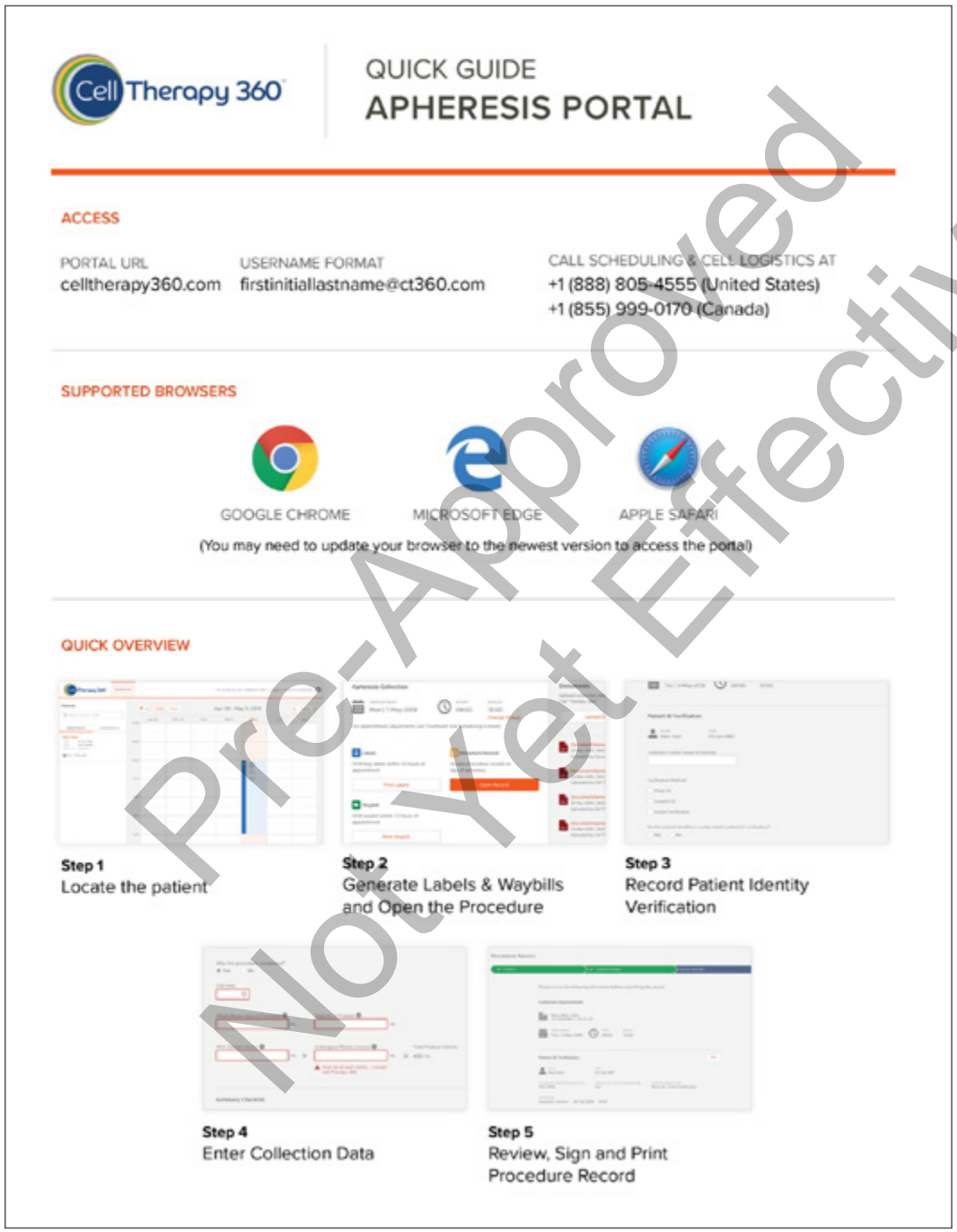
Approver Name (user name): Liz Lemon

Date & Time of Signature[1]: 04-SEP-2020 12:25 TZ

[1]Time requires time zone and represents the time zone where the activity took place

Attachment E

Cell Therapy 360 Apheresis Portal Summary



Cell Therapy 360

QUICK GUIDE
APHERESIS PORTAL

ACCESS

PORTAL URL
celltherapy360.com

USERNAME FORMAT
firstinitiallastname@ct360.com

CALL SCHEDULING & CELL LOGISTICS AT
+1 (888) 805-4555 (United States)
+1 (855) 999-0170 (Canada)

SUPPORTED BROWSERS

GOOGLE CHROME MICROSOFT EDGE APPLE SAFARI

(You may need to update your browser to the newest version to access the portal)

QUICK OVERVIEW

Step 1
Locate the patient

Step 2
Generate Labels & Waybills and Open the Procedure

Step 3
Record Patient Identity Verification

Step 4
Enter Collection Data

Step 5
Review, Sign and Print Procedure Record

Version History

Version No. 1.0	**Effective Date:** Current
Quality Event Number:	QE-074058

Version History:

- Consolidated JSP-001012: Adult Clinical MNC Collection Procedure – North America & JSP-001018: Adult Commercial MNC Collection Procedure – North America.
- Updated photos and images
- Added Quick Reference Guide
- Updated to Interactive PDF format
- Updated partner to 2SeventyBio, Inc.
- Made updates in alignment with RISK-011536 v 2.0
- Re-arranged sections of MNC Collection Procedure
- COI checks updated: removed Waybill verification
- Consolidated REF-001774: Marken Courier Amendment to MNC Collection Procedures - Global (v5.0)
- Added commercial drug names throughout
- Added verbiage to avoid overcollection