Poseida Therapeutics, Inc.

Cellular Therapy Lab and P-CD19CD20-ALLO1 Administration Manual

Protocol Number

P-CD19CD20-ALLO1-001

Version 1: 10 May 2023

TABLE OF CONTENTS

1. INTRODUCTION

This manual describes Poseida Therapeutics, Inc. (Poseida) investigational product P-CD19CD20-ALLO1 shipment, tracking, storage, and administration for the study entitled: Open-Label, Multicenter, Phase 1 Study to Assess the Safety of P-CD19CD20-ALLO1 in Subjects with Selected Relapsed/Refractory B cell Malignancies.

Forms described in this document and samples attached as appendices include:

- **P-CD19CD20-ALLO1-001 Dose Infusion Authorization Form (**Appendix 1) – This form will be completed and provided by Poseida. The form requires principal investigator (PI) review and approval before dose administration.
- **P- CD19CD20-ALLO1-001 Dose Administration Form (**Appendix 2) – This form is to be completed by the site staff preparing and administering the dose.
- **P- CD19CD20-ALLO1-001 Investigational Product Destruction Form (**Appendix 3) – This form should be completed in the event P- CD19CD20-ALLO1 requires destruction on-site.
- **Poseida Allogeneic Product Chain of Custody Form (**Appendix 8) **–** This form will be completed for each shipment of Investigational Product (IP) shipped to and received at a site.

2. PERSONNEL

Sponsor – Poseida Therapeutics, Inc.

Name	Title	Email	Phone
Rajesh Belani, MD	Vice President, Clinical Development	rbelani@poseida.com	+1 760 276 3198
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Kayla Shaw	Logistics Coordinator II	logistics@poseida.com	+1 858 926 7360

3. PRODUCT DESCRIPTION - P-CD19CD20-ALLO1

P-CD19CD20-ALLO1 is comprised of allogeneic CAR-T cells that target both CD19 and CD20 and have been genetically modified using an electroporation-based, non-viral (DNA transposon) gene delivery system called the piggyBac® (PB) DNA modification system and the Cas-CLOVER™ gene editing system. The primary attributes of P-CD19CD20-ALLO1 are conferred by the genes introduced in the PB transposon, including anti-CD19 and anti-CD20 targeting variable human heavy-chain domains (VH)-based CAR (VCAR) gene, a dihydrofolate reductase (DHFR) selection mutant protein (mutein) gene, and an inducible caspase-9 (iCasp9)-based safety switch gene, and the genes ablated using the Cas-CLOVER™ gene editing system, the T cell receptor beta chain (TRBC) and beta-2-microglobulin (B2M) genes.

There are 2 CAR expression cassettes, one is composed of an extracellular CD19-binding VH protein fused to a CD8α spacer, a CD8α transmembrane domain, an intracellular 4-1BB signaling domain and a CD3ζ signaling domain. The second CAR expression cassette is composed of an extracellular CD20-binding VH protein fused to a CD8α spacer, a CD8α transmembrane domain, an intracellular 4-1BB signaling domain and a CD3ζ signaling domain.

4. FORMULATION

P-CD19CD20-ALLO1 drug product consists of cells formulated in a sterile, cryopreservation medium containing 50% (v/v) PLASMA-LYTE A and 50% (v/v) CryoStor® CS10.

5. HOW SUPPLIED

P-CD19CD20-ALLO1 is manufactured by Poseida under cGMP conditions. P-CD19CD20-ALLO1 is an off-the-shelf product with release testing performed and a Certificate of Analysis (COA) provided for each lot. P- CD19CD20-ALLO1 is supplied frozen at ≤ -130°C in a 20mL "AT-Closed Vial®" with each vial containing approximately 20 mL of P- CD19CD20-ALLO1 at a concentration of 8 x 10^6 cells per mL. P- CD19CD20-ALLO1 vials are shipped to the clinical site in a cryogenic shipping container.

The following is an example of the labeling of P-CD19CD20-ALLO1. Each product vial will be labeled with product name, date of manufacture, lot number, concentration, storage conditions, donor identification number (DIN) and part number. In addition, the product vials will be labeled with the following for caution: "Caution: New Drug—Limited by Federal (or United States) law to investigational use." Each final product vial will be numbered sequentially starting with 001.

Figure 1: Primary labeling (Example):

Vol: 20 mL Vial: XXX[1] DIN #: XXXXXXXXXXXXX[2]
Store at ≤ -130°C

See Infusion Authorization Form for Dose

P-CD19CD20-ALLO1 Conc. 8 x 10^6 cells/mL

Part #: XX.XXX[3] Lot #: XXXXX[4]
DOM: DDMMMYYYY[5]

Manufactured by Poseida Therapeutics
Protocol #: P-CD19CD20-ALLO1-001
Caution: New Drug--Limited by Federal (or United States) law to investigational use

EVALUATED FOR INFECTIOUS SUBSTANCES

- [1]Vial XXX: Vial number starting with 001
- [2]DIN: Donation Identification Number, 13-digit identifier (facility ID number, year and sequence number) eye readable text below the barcode, do not include the flag and check character
- [3]Part#: Variable field, unique identifier assigned by Poseida
- [4]Lot#: Variable field, unique identifier assigned by Poseida
- [5]DOM: Date of Manufacture defined as the date of final drug product formulation

Supplies

Sites will provide all ancillary supplies such as infusion bags, latex free, non-filtered blood product compatible infusion sets and normal saline.

Poseida will supply the AT-Adapt, needle-less collection device for AT-Closed Vial which should be used to extract cells from the AT-Closed Vial.

To minimize variability, the BD alaris pump infusion set (manufacturer number 2426-0007), or the McKesson administration set (manufacturer number SF3258-10H) is recommended. Please contact your ICON Clinical Research Associate (CRA) or ICON Clinical Trial Manager (CTM) or Poseida if you are not able to use the infusion sets or other equipment listed above.

6. P-CD19CD20-ALLO1 SHIPMENT AND RECEIPT

Receipt of Transport Dewar

P-CD19CD20-ALLO1 will be supplied in an appropriately sized vapor phase liquid nitrogen cryogenic shipping system (transport dewar) at ≤ -130°C prior to the start date of conditioning

chemotherapy. The product will be shipped in either a Cryoport or Biolife DV10 transport Dewar. Please see Appendix 4 or Appendix 6, as applicable, for instructions on transport Dewar receipt/unloading/return.

Please see Appendix 5 or Appendix 7, as applicable, for instructions on transport Dewar temperature information.

Condition Verification

Inspect the dewar for external damage such as large dents. Verify no major frost or condensation on outside of unit, which could indicate either a complete or partial loss of vacuum and potential damage to the vial(s). If frost/condensation found, please contact logistics@poseida.com, the Poseida Clinical Trial Manager (CTM), and your CRA immediately.

Check temperature log to ensure no significant temperature changes occurred during transportation. When removing the vial(s) from the transport dewar, inspect the vial contents and appearance. If the product experienced a temperature excursion or is not in good condition (such as cracks or any abnormalities), immediately contact logistics@poseida.com, the Poseida CTM, and your ICON CRA immediately.

When possible, please photograph damage or other abnormalities and provide the images to Poseida.

Receipt/Unloading Documentation:

1. Complete Section 4 of the accompanying Poseida Allogeneic Product Chain of Custody form in Appendix 8.
2. **Verify** the items are in good condition, all documentation was received, and primary identifiers match the documentation.
   - **Sign & Date** to confirm your inspection.
   - **Scan and return** the form to the email indicated on the form.
3. On the day of the receipt, transfer P-CD19CD20-ALLO1 into vapor phase liquid nitrogen freezer or equivalent that steadily maintains the temperature of ≤ -130°C.
4. A Dose Infusion Authorization (DIA) Form (Appendix 1) will be provided by Poseida typically within a few days of subject enrollment. Once the DIA is received, please confirm you received sufficient product to administer the calculated dose.

7. STORAGE

Vials containing P-CD19CD20-ALLO1 cells should be stored at the site in blood bank/cell processing center conditions in a monitored ≤ -130°C vapor phase cryogenic freezer or equivalent until the subject is ready for infusion.

8. STABILITY

P-CD19CD20-ALLO1 cells should ideally be infused within 2 hours of thawing the final product vial. The maximum stability assessed is 4 hours at 2° to 8°C. Please contact your ICON CRA or CTM or Poseida to confirm stability outside of these conditions.

9. PHASE AND COHORT DOSE ADMINISTRATION

This is a Phase 1 open label study. P-CD19CD20-ALLO1 will be administered intravenously as a single dose. Dose levels will be tested by cohort in the 3+3 escalation design described in Section 3.1 of the protocol. You will receive the confirmed cohort assignment on the signed DIA Form (Appendix 1) on or before the start of conditioning chemotherapy.

10. ADMINISTRATION, HANDLING AND DISPOSAL

P-CD19CD20-ALLO1 contains allogeneic human T cells from healthy donors; site staff should utilize universal precautions to prevent transmission of blood borne infections as outlined by the Center for Disease Control and Prevention(http://www.cdc.gov/niosh/topics/bbp/universal.html). Procedures for handling live human cells should be followed per the local institutional policy and process.

Aseptic technique must be followed for all steps involving products for administration to immunocompromised patients.

P-CD19CD20-ALLO1 is administered on Day 0 (per clinical study protocol), two days after the last dose of conditioning chemotherapy.

After a subject is enrolled, an approved P-CD19CD20-ALLO1 DIA Form (Appendix 1) will be sent to the investigative site providing the assigned arm, dose and the total volume of P-CD19CD20-ALLO1 cells to be administered. Confirm that the product, quantity of product and COA you have received match the information on this form (note in particular that each vial of P-CD19CD20-ALLO1 contains approximately 20 mL and you should have enough vials to provide at least the required total volume for infusion as outlined on the DIA form).

During administration and processing, record all requested information on the P-CD19CD20-ALLO1 Administration Form in Appendix 2. You will need one form for each vial.

10.1 Thawing

Whether single or multiple vials are required for the infusion, it is intended that P-CD19CD20-ALLO1 cells be infused within 2 hours of thawing. Vials should be thawed using a water bath at 36° to 38°C, with the vial(s) placed inside a sterile bag in case of a leak and to prevent contamination of the vial(s). In case multiple vials are required to be thawed, no more than 2 vials should be thawed simultaneously.

The vials will be submerged in the water bath and gently swirled continuously until the cells have been fully thawed. There must be no frozen clumps left in the vial(s). Vial thaw time will

depend on the size and type of water bath used but will generally take 10-20 minutes. If thawing is taking longer than 20 minutes, contact Poseida to discuss methods for thaw time reduction. If your site experiences longer thaw times with two vials thawed simultaneously, it may be preferable to thaw one vial at a time; please contact Poseida with any questions. If a vial appears to be damaged, leaking or otherwise compromised, do not proceed with the infusion and contact Poseida immediately for guidance.

In case of unforeseen circumstances, thawed cells may be stored at 2° to 8°C for up to 4 hours. For each vial, record thawing start and end time and duration of storage between thawing and dosing.

DO NOT maintain the cells outside of 2° to 8°C once thawed. Record the water bath temperature on the P-CD19CD20ALLO1 Administration Form Appendix 2**.**

10.2 Preparation

P- CD19CD20-ALLO1 can be prepared in the cell therapy lab or other appropriate facility.

Depending on your institution and the volume to be infused, P- CD19CD20-ALLO1 may be administered intravenously by infusion pump, gravity or syringe.

For volumes less than 16mL:

Cells may be thawed in the cell therapy lab and delivered via syringe appropriate for the dose and volume.

- For infusion of dose volumes <16 mL, it is recommended to use an appropriately sized syringe. See Table 1.

Table 1: Recommended Small Volume Syringes based on Dose Volume

Dose Volume	Recommended Syringe Size
>10 mL to < 16 mL	20 mL syringe
>5 mL to ≤ 10 mL	10 mL syringe
>1 mL to ≤ 5 mL	5 mL syringe
>0.5 mL to ≤ 1 mL	1 mL syringe
≤ 0.5 mL	0.5 mL syringe

For larger volumes (equal to or greater than 16mL):

The dose may be prepared in the cell therapy lab by combining multiple vials into one infusion bag and brought to the bed side refrigerated and delivered via infusion pump or gravity.

Prior to each infusion, the vials required for that infusion may be transferred at ≤ -130°C and thawed, aliquoted into appropriate volumes dictated by the DIA Form in a pharmacy, cell processing lab or other appropriate facility.

Thawed P-CD19CD20-ALLO1 may be transported (in a secondary container such as infusion bag or syringe) to the bedside at 2° to 8°C (contact Poseida if other transport conditions or temperatures are needed).

Thawed cell suspension should be removed gently by using the provided AT Adapt needle-less device (https://www.aseptictech.com/products/adapttm) and connecting the appropriate syringe to the luer lock tip:

- Gather AT-Closed Vial, syringe and AT-Adapt device
- Remove the flip top

- Remove the protective cover from the AT-Adapt device

- Firmly press the AT-Adapt device on to the AT-Closed Vial to pierce the stopper.

- Lift the AT-Adapt device until the lower tab touches the cap bead

- Remove the protective cover of the luer connection. Attach a syringe to the vial using the luer lock on the AT-Adapt device and withdraw product.
- Video of how to use the AT-ADAPT™ device for the AT-Closed Vial®:

  https://www.youtube.com/watch?v=pbwgZVqV2Yk

If the total volume from the number of vials provided exceeds the assigned dose for the subject, draw up and administer only the volume of product corresponding to the assigned dose. If a sufficient number of vials have not been provided for a volume of the product corresponding to the assigned dose for the subject, contact Poseida to determine the next step. The product may be held in storage to combine with a subsequent shipment if it has been maintained at ≤ -130ºC without thawing. Or, upon approval from Poseida, the product may be administered immediately, however the dose for that subject will be recorded as the dose received, not the prescribed or cohort assigned dose, and all data from that subject analyzed accordingly.

10.3 Infusion

Emergency medical equipment (i.e., emergency trolley) must be available during the infusion in case the subject has an allergic response, severe hypotensive crisis, or any other reaction to the infusion. An intensive care unit should be within a reasonable distance of the investigational drug administration location.

P- CD19CD20-ALLO1 will be administered intravenously by infusion pump, gravity or syringe via non-filtered tubing as follows:

- Record infusion start time on the P-CD19CD20-ALLO1 Administration Form (Appendix 2)
- P- CD19CD20-ALLO1 should be infused at a flow rate of approximately 1 to 20 mL per minute through an appropriate **non-filtered** blood infusion set as appropriate for the dose and volume. The duration of the infusion should be approximately 1 to 20 minutes, based on the volume.
- Flush venous line with normal saline (no heparin) to keep open (TKO).
- Spike product bag with non-filtered tubing set with flow regulator (but no clamps) or attach syringe containing P- CD19CD20-ALLO1 cells if delivering via syringe push/pump.
- Prime line carefully to avoid allowing any cells to flow out before connecting to patient venous access. Record the P- CD19CD20-ALLO1 infusion start time on the P- CD19CD20-ALLO1 Administration Form (Appendix 2).
- The bag or syringe should be gently agitated during P- CD19CD20-ALLO1 infusion to prevent cell clumping.
- If the entire contents of the bag or syringe will be infused by gravity, a slow push may be used if necessary.

- Repeat process if multiple bags or syringes are necessary to provide the prescribed dose.
- If the entire contents of a bag or syringe have been administered, if possible, back flush the bag or syringe with normal saline and infuse it while maintaining a closed tubing system to minimize the number of cells unintentionally retained in the bag or syringe.
- After the entire dose is infused, the tubing should be flushed at the same infusion rate with at least 20 mL normal saline (no heparin) to ensure all P- CD19CD20-ALLO1 is delivered.
- Record the P-CD19CD20-ALLO1 infusion completion time and the volume delivered on the P- CD19CD20-ALLO1 Administration Form (Appendix 2).

10.4 Disposal

The vial label(s) should be copied or photographed for ICON CRA review prior to disposal if institutional SOPs/guidelines allow. Destroy any unused cells according to institutional SOPs/guidelines. Empty vials and/or remaining cells should be disposed of per institutional biosafety guidelines and documented in the Investigational Product Destruction Form (Appendix 3). In the event of unused or damaged product/packaging, Poseida should be contacted immediately to determine disposition.

11. QUESTIONS AND CONCERNS

Please contact your ICON CRA and CTM or Poseida prior to enrolling patients if institutional standards are different from those listed above.

Non-emergency study related questions or concerns should be directed to your assigned ICON CRA. Please copy the ICON Clinical Trial Manager along with Preety Grewal, Poseida Sr. Clinical Trial Manager, Clinical Operations.

Questions that are critical or time sensitive may be directed to:

Primary Medical Monitor
Rajesh Belani, MD
Vice President, Clinical Development
+1 760 276 3198
rbelani@poseida.com

APPENDIX 1. P-CD19CD20-ALLO1 DOSE INFUSION AUTHORIZATION FORM

Protocol P-CD19CD20-ALLO1-001
P-CD19CD20-ALLO1 Dose Infusion Authorization Form

Subject ID: _____ Product Lot Number: _____

Subject Weight (kg) at Screening: _____ Date of Manufacture: _____

Poseida will perform the calculations below to determine the maximum allowable infusion dose (MAID) required for P-CD19CD20-ALLO1 and provide the completed form to the site.

		Result	Unit
A'	% CD19 and CD20 dual-positive CAR Expression (results from CofA)		%
B'	% Residual CD3+ (results from CofA)		%
C'	Maximum allowable CD3+ cells/kg (FDA guidance)	70,000	cells/kg
MAID	Max. Allowable Infusion Dose $\left(\frac{C' * A'}{B'}\right)$		cells/kg

Cohort Number: _____ Cohort Dose (A): _____ x 10^6 cells/kg

If Cohort Dose (**A**) _____ > MAID _____: Do not proceed
If Cohort Dose (**A**) _____ ≤ MAID _____: Proceed to table below

Poseida will perform the calculations below to determine the infusion dose required for P-CD19CD20-ALLO1 and provide the completed form to the site.

The investigative site will infuse the Total Volume for Infusion per Line G below.

A completed form, with both signatures, must be received prior to infusing the product into a subject.

		Result	Units
A	Dose in P-CD19CD20-ALLO1 cells/kg (Cohort Dose)		cells/kg
B	Subject Weight (kg)		Kg
C	Total P-CD19CD20-ALLO1 cells Required _____ (**A**) X _____ (**B**)		cells
D	% CD19 and CD20 dual-positive CAR Expression (results from CofA)		%

APPENDIX 2. P-CD19CD20-ALLO1 ADMINISTRATION FORM

Protocol P-CD19CD20-ALLO1-001
P-CD19CD20-ALLO1 Dose Infusion Authorization Form

E	Total Cells Required for Infusion [(C÷D) x 100%] $\frac{\text{C}}{\text{C}} \div \frac{\text{D}}{\text{D}} \times 100$		cells
F	Viable Cell Concentration (from CofA)		cells/mL
G	Total Volume for Infusion (mL) $\frac{\text{E}}{\text{E}} \div \frac{\text{F}}{\text{F}}$		mL

Poseida Medical Monitor Approval: _____ Date: _____

Poseida Quality Assurance Approval: _____ Date: _____

Investigative site personnel should review the calculations presented in the table above.

Dose Preparation/Infusion Personnel Approval: _____ Date: _____

Principal Investigator Approval: _____ Date: _____

The completed form should be filed at the site with the subject's source documentation.

APPENDIX 3. INVESTIGATIONAL PRODUCT DESTRUCTION FORM

P-CD19CD20-ALLO1-001 DESTRUCTION FORM (For Any Unused Product)

Principal Investigator Name:		Site Number:	

Investigational Product Number	Lot Number and Part Number	Date of Manufacture	Vial Number
P-CD19CD20-ALLO1			
P- CD19CD20-ALLO1			
P- CD19CD20-ALLO1			
Pharmacy or other designated organization performing destruction (name and address):			
This is to certify that all material has been destroyed in accordance with local regulations.			
Company/Pharmacy Representative: Signature: Print Name/Title: Date (DD MMM YYYY):			

APPENDIX 4. TRANSPORT DEWAR INSTRUCTION – RECEIPT / UNLOADING OF CRYOPORT

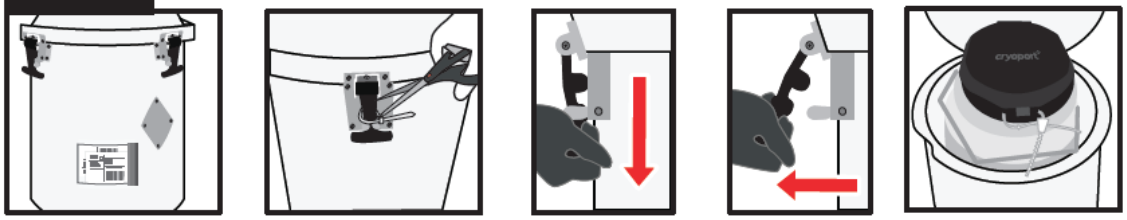
cryoport
SCIENCE. LOGISTICS. CERTAINTY.

HOW TO UNLOAD NON-INFECTIOUS SAMPLES | SIDE 1
GENERAL PURPOSE SHIPPER

HIGH VOLUME SHIPMENT: UNLOADING NON-INFECTIOUS SAMPLES

SECTION A RECEIVING SHIPPER

STEP 1 UNLATCHING INSTRUCTIONS



Once the shipper has arrived, remove old shipping pouch and zip-ties.

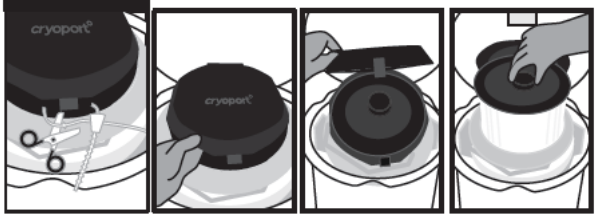
Remove zip-ties from both black handles with scissors.

Unlatch both sides by pulling black handle down & away from the shipper.

Open lid to expose the dewar.

SECTION B UNLOADING SAMPLES FROM SHIPMENT

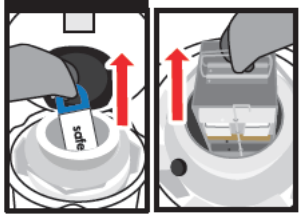
STEP 1



Cut off the zip tie on the hinged cap with scissors.

Open the hinged cap by pulling up on one of the two lift handles on the lid. With gloved hands, pull up on the circular handle in the center of the vapor plug to remove the vapor plug. Set the vapor plug aside.

STEP 2



With gloved hands, remove the loaded commodity by pulling upwards.

STEP 3

Place any returnable accessories back into the dry shipper.

SECTION C PACKAGING THE SHIPMENT

STEP 1

Replace the vapor plug.

STEP 2

Close the hinged cap by pulling down on the lid.

STEP 3

Secure the hinged cap with a zip tie.

STEP 4

Remove the Leg 3 shipping pouch from the document protector attached to the dewar handle inside of the container.

STEP 5

Remove the EMPTY label from the shipping pouch and place on the metal diamond.

IF THE DRY SHIPPER DOES NOT EMIT VAPOR WHEN PLUG IS REMOVED
PLEASE CONTACT CUSTOMER SERVICE IMMEDIATELY, BY CALLING (949) 470-2305 OR EMAIL CS@CRYOPORT.COM

cryoport
SCIENCE. LOGISTICS. CERTAINTY.

HOW TO UNLOAD NON-INFECTIOUS SAMPLES | SIDE 2
GENERAL PURPOSE SHIPPER

HIGH VOLUME SHIPMENT: UNLOADING NON-INFECTIOUS SAMPLES

SECTION C PACKAGING THE SHIPMENT (CONTINUED)

STEP 6 Remove the commercial invoices located in the shipping pouch.

International Shipments ONLY

Sign and date.

Return all documents being shipped behind the Air Waybill Including any: Permits, Forms, Licenses, etc.

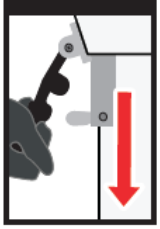
STEP 7 Once all documents are loaded:

Close the shipping pouch and remove sticker backing.

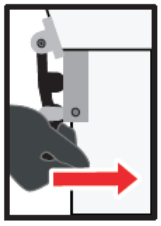
Place shipping pouch on the enclosure's metal plate.

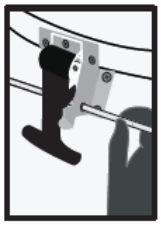
Close the enclosure lid.

STEP 8 LATCHING INSTRUCTIONS



Latch handle on both sides by pulling the black handle down & then towards the shipper.

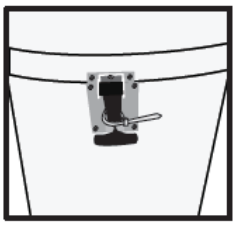




Insert zip-tie through one of the holes on the metal latch hardware.

Thread end of zip-tie through the hole on the other side of the metal hardware.

Insert zip-tie through the lid buckle and tighten.



Zip-tie is now securely around the black handle.

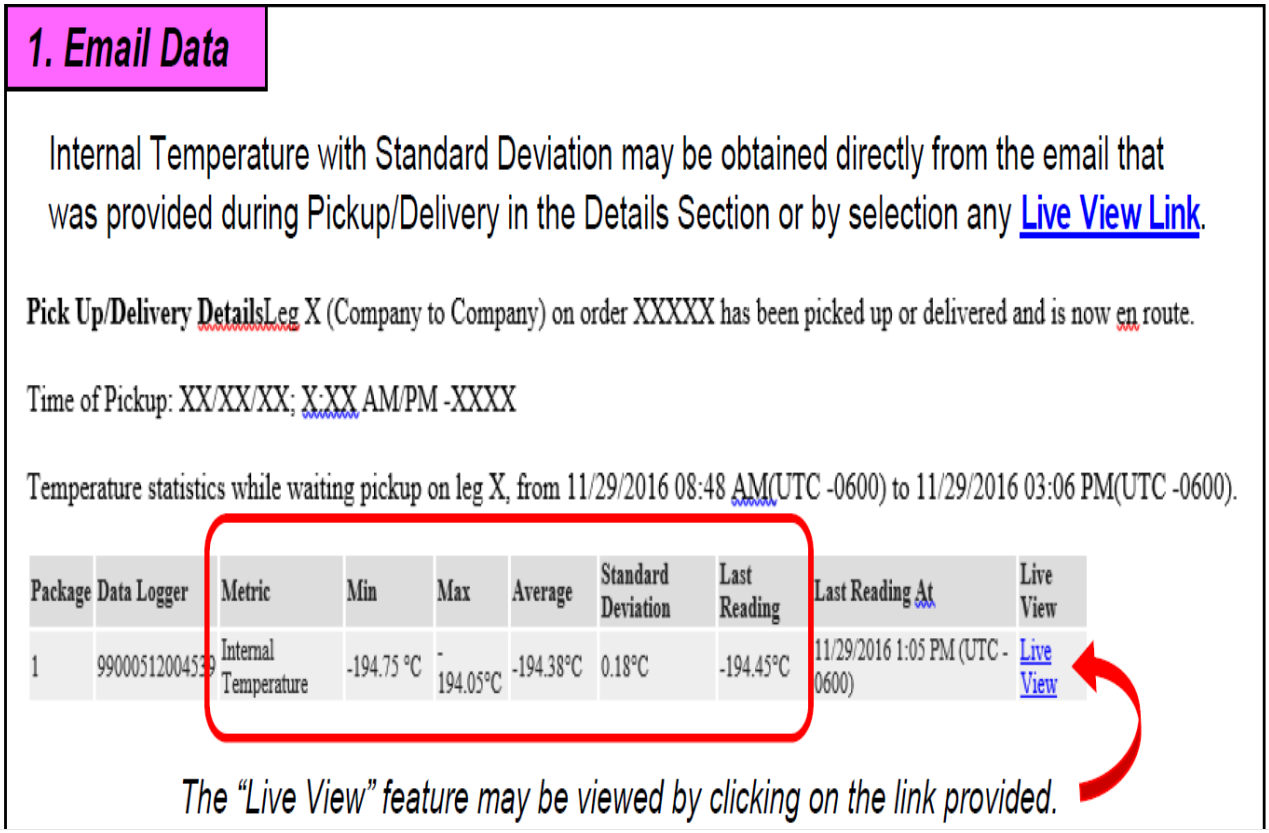
For those shipments containing regulated dangerous goods/hazardous materials, the shipper is responsible for correctly preparing the shipment according to the current International Air Transport Association (IATA) and International Civil Aviation Organization (ICAO) dangerous goods regulations.

This includes correct identification, classification, packaging, dangerous goods markings and labeling as well as completion of all pertinent and required documentation. The shipper is the customer who is preparing the shipment at each leg in the transportation of the dry dewar packaging.

24-hour Help Line
(949) 470-2305

Cryoport, Inc. • 17305 Daimler St. • Irvine, CA 92614
Phone: 1-949-470-2300 | Fax: 1-949-470-2306
www.cryoport.com • e-mail contact: cs@cryoport.com

APPENDIX 5. TRANSPORT DEWAR INSTRUCTION – TEMPERATURE INFORMATION FOR CRYOPORT



APPENDIX 6. TRANSPORT DEWAR INSTRUCTION – RECEIPT / UNLOADING OF BIOLIFE DV10

Section A: Receiving shipper

Step A1	RETRACT HANDLE Push the handle button and push the top of the handle down until fully retracted. Retracting the handle will ensure unencumbered access to the shipper. 
Step A2	REMOVE SECURITY SEAL (if applicable) If using a security seal to prevent the opening of the shipper lid, cut and remove it  OPEN SHIPPER CASE LID Once the security seal has been removed, pull both zippers away from each other until the lid can be opened.

Section B: Unloading Samples

Step B1	<u>REMOVE SMART CAP FROM SHIPPER</u> Carefully cut and remove the security seal that attaches the Smart Cap to the security loop around the dewar neck. Pull up with both hands to slide the Smart Cap out of the dewar neck. PLEASE NOTE, proper placement of the DV10 Smart Cap when not seated in the dewar body is PROBE SIDE UP. Serious damage to the probe may occur if placed otherwise 
Step B2	<u>REMOVE EXTRACTOR FROM DV10 CORE</u> (if applicable) Grabbing the handles of the Biolife General Extractor wearing appropriate protective equipment, pull up firmly to remove from the DV10 shipper. Unpack and store payload according to the manufacturer's instructions.

Place any returnable accessories back into the shipper.
After lowering the general extractor into DV10 core, confirm that the handle is lying flush with the top of the extractor to mitigate damage to the DV10 SmartCap.

OR

REMOVE MODPAK FROM DV10 CORE (if applicable)
Grabbing the handles of the ModPak wearing appropriate protective equipment, pull up firmly to remove from the DV10 shipper.

Unpack and store payload according to the manufacturer's instructions.

Step B3

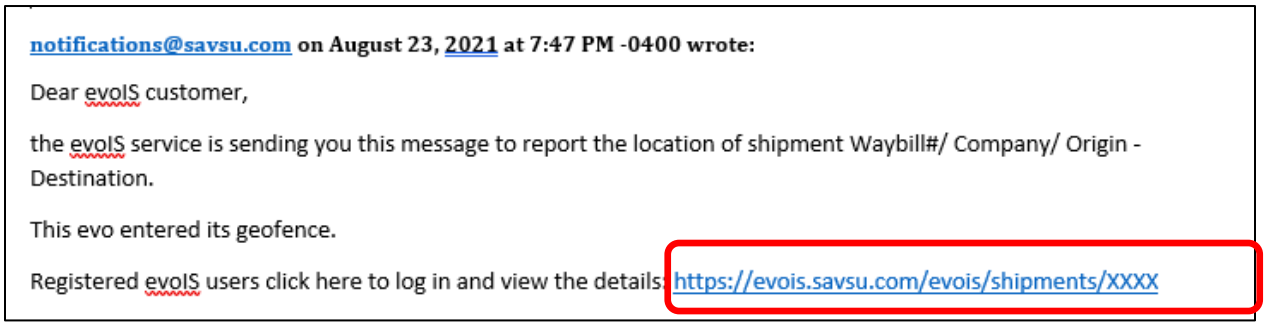
PLACE SMART CAP BACK ON DV10
Firmly set Smart Cap into the neck of the Dewar to prevent damage to the unit.

ZIP UP LID & CLOSE OUTER BOX.
Prepare the DV10 for return shipment by closing the shipper Outer Pack lid with the zipper closures.

	 10 DV10

APPENDIX 7. TRANSPORT DEWAR INSTRUCTION – TEMPERATURE INFORMATION FOR BIOLIFE DV10

Internal temperature may be obtained through the e-mail that was provided during transport / delivery.



notifications@savsu.com on August 23, 2021 at 7:47 PM -0400 wrote:

Dear evoIS customer,

the evoIS service is sending you this message to report the location of shipment Waybill#/ Company/ Origin - Destination.

This evo entered its geofence.

Registered evoIS users click here to log in and view the details: https://evois.savsu.com/evois/shipments/XXXX

EvoIS non-registered users could be provided with external link for monitoring.

APPENDIX 8. POSEIDA ALLOGENEIC PRODUCT CHAIN OF CUSTODY FORM

Poseida Allogeneic Product Chain of Custody

Section 1. Poseida Logistics to complete clinical site identification.			
Protocol: _____	**Principal Investigator:** _____ *First Name* *Last Name*		
Site ID: _____	**Expected Product Receipt Date:** _____ DD/MMM/YYYY		
Completed By:	Print:	Sign:	Date:

Section 2. Poseida Logistics to complete shipment information.		
Shipment Courier: _____	**Courier Bill of Lading #:** _____	
Drug Product Packaging Type: ☐ Vial ☐ Bag	**Number of Units to be Shipped:** _____	**Lot Number:** _____
Ship From (Name and Address): ☐ Manufacturing Site ☐ Storage Depot ☐ Other _____	**Ship To (Name and Address):** ☐ Clinical Site ☐ Storage Depot ☐ Other _____	
Institution Name: **Address:** **City/State:** **Country/Zip code:** **Contact:** **Tel/E-mail:**	**Institution Name:** **Address:** **City/State:** **Country/Zip code:** **Delivery contact:** **Tel/E-mail:**	
Completed By:	Print:	Sign: Date:

Section 3. Shipper to complete final product manufacturing and pack-out information. ****Contact Poseida for any issues or concerns that may arise.****		
Number of Units Packed: _____	**Lot #:** _____	**Unit(s) ID #:** _____
Mfg Date: _____ DD/MMM/YYYY	**Mfg Vol. per unit:** _____ mL	**Part #:** _____
Pack-Out Date: _____ DD/MMM/YYYY	**Pack-Out Time:** _____ : _____ 24-hour clock	**Time Zone:** ☐Pacific ☐Mountain ☐Central ☐Eastern ☐Other: _____
LN_2 Shipper #: _____	**Data Logger Serial #:** _____	**Dewar Serial Tag #:** _____
Completed By:	Print:	Sign: Date:
Verified By:	Print:	Sign: Date:

Poseida Allogeneic Product Chain of Custody

Section 4. Receiving site to complete final product receipt information upon delivery to Pharmacy or Designated Facility.		
Has the LN_2 shipper arrived in good condition?		☐Yes ☐No
Date of Receipt of LN2 shipper: _____ DD / MMM /YYYY	**Time of Receipt:** _____ : _____ 24-hour clock	**Time Zone:** ☐Pacific ☐Mountain ☐Central ☐Eastern ☐Other: _____
Record shipper temperature at arrival _____°C	**Dewar Serial Tag #:** _____	
After reviewing the temperature log, has the LN2 shipper maintained the required temperature range during transport?		☐Yes ☐No
Number of Units Received: _____	**Lot #:** _____	**Unit(s) ID#:** _____
After inspection, is the drug product received in good condition?		☐Yes ☐No
Has the transfer of drug product into the vapor phase nitrogen freezer occurred?		☐Yes ☐No
Date of Transfer into vapor phase nitrogen freezer: _____ DD / MMM /YYYY	**Time of transfer:** _____ : _____ 24-hour clock	**Time Zone:** ☐Pacific ☐Mountain ☐Central ☐Eastern ☐Other: _____
If the answer is "No" to any of the questions in Section 4, please list the issues below and contact Poseida immediately.		
Completed By:	Print: Sign:	Date:

Please scan and return completed form to Poseida Logistics at logistics@poseida.com upon receipt.