CELL THERAPY MANUAL

(FOR USE WITH AT-CLOSED® CRYOVIALS)

PROTOCOL NUMBER:	**P-105-201**
DATE:	**09-MAY-2022**
VERSION:	**4.0**
COUNTRY SPECIFIC:	**USA**

APPROVERS:

_____

Tanuj (Kenny) Kamineni,
Clinical Operations

_____

Tim Hanson, Supply Chain

_____

William Marshall, Clinical Development

Version History

Date	Version Number	Summary of Changes
24-NOV-2020	V 1.0	• Original
14-JUL-2021	V 2.0	• Implementation of the JUDI system for submission of HLA reports • Removal of needleless connectors (e.g., Clave™) • Designation of transport of the investigational product at room temperature • Priming of syringe filters at cell therapy lab or bedside • Change in extension tubing for use with peripheral intravenous catheters • Transition to new manual template and additional edits for clarity
05-Nov-2021	V3.0	• Implementation of updated cryovials (AT Closed Vials®) and AT-Adapt™ single-use needleless connection device. • Deleted 16-gauge blunt end needle • Updated instructions on destruction of investigational product • Updated what can be used if patients develop post-infusion reactions • Administrative changes throughout including appendices updated: o Removed cryoshipper label section from chain of custody form o Moved secondary label section from dose worksheet to chain of custody form • Removed FlexAdvatage IRT site user reference guide as an attachment
09-May-2022	V4.0	• Change in name of Brooks to Azenta • Change in name of Cognate to Charles River Laboratories

Date	Version Number	Summary of Changes
		• Added information on using AT-Adapt™ • Added Appendix for AT-Adapt™ user guide • Added section E to Issue Reporting Form • Added dose volume confirmation to Dosing Form • Updated ICON and AlloVir Staff and Role Changes • Administrative edits

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1 CONTACTS

The parties involved in the processes outlined in this manual, and their corresponding roles, are listed in the table below.

Party Involved	Role
AlloVir	Sponsor
ICON	Contract Research Organization (CRO)
United States Azenta US, Inc.	GMP Storage Facility
Cryoport	Cold Chain Logistics (IP shipment from regional storage facility to site)
Charles River Laboratories, Inc.	Drug Product CDMO
ICON	CRO operating CytoMatch and JUDI HLA Adjudication system

For issues which may arise during the conduct of this study, the appropriate contact is listed below.

Issue	Contact
General Issues	Primary: Issue Reporting Form emailed to ICON CRA & ICON CTM
Dose shipment, preparation or dosing issues that require immediate attention	Primary: Francesca Cardarelli (AlloVir Medical Monitor) Alternates: ICON CRA & ICON CTM, AlloVir Regional Site Liaison
FlexAdvantage IRT System technical issues	Primary: ICON IRT 1-888-426-8801 Non-Urgent: icophone@iconplc.com

Direct contact information for study team members is listed below. Please note that study contacts may change. Contact information for the study team (including CRAs) can be found in the Site Regulatory Binder. For all communications regarding cellular product, please include your site assigned ICON CRA.

AlloVir Study Team	ICON Study Team
Francesca Cardarelli, MD Lead Medical Monitor / Director, Clinical Development +1 781- 460-3670 fcardarelli@allovir.com	**Lia Bond** Senior Clinical Trial Manager +1 615-372-3945 lia.bond@iconplc.com
Bill Marshall, MD Back-up Medical Monitor / Vice President, Clinical Development +1 617-990-2626 bmarshall@allovir.com	**Mary Alas** Unblinded Clinical Trial Manager +1 215-317-2979 mary.alas@iconplc.com
Kenny Kamineni Associate Director, Clinical Operations +1 650-546-1510 kkamineni@allovir.com	**Chad Crafford** Dry Run and Supplies Manager +1 919-748-8721 charles.crafford@iconplc.com
Anna Brooks Associate Director, Clinical Operations Management +1 716-908-6556 abrooks@allovir.com	**Casie Asmus** Senior Program Manager +1 215-583-2917 casie.asmus@iconplc.com
	ICON Help Desk +1-888-426-8801 icophone@iconplc.com

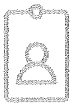
2 ABBREVIATIONS, TERMS, AND DEFINITIONS

Abbreviation	Definition
AABB	Formerly known as American Association of Blood Banks
CAR	Chimeric antigen receptor
CDMO	Contract development and manufacturing organization
CRA	Clinical Research Associate
CRO	Contract research organization
CRS	Cytokine Release Syndrome
CTM	Clinical Trial Manager
DMSO	Dimethyl sulfoxide
eCRF	Electronic case report form
FACT	Foundation for the Accreditation of Cellular Therapy
GMP	Good Manufacturing Practice
GVHD	Graft versus host disease
HCT	Hematopoietic cell transplant
HLA	Human leukocyte antigen
IP	Investigational product
IRT	Interactive response technology
ISF	Investigator Site File
IV	Intravenous, -ly
JACIE	The Joint Accreditation Committee International Society for Cellular Therapy - Europe & the European Society for Blood and Marrow Transplantation
LN2	Liquid nitrogen
ML/MM	Medical Lead/Medical Monitor
PM	Project Manager
PSL	Posoleucel (ALVR105)
SDS	Safety data sheet
SOP	Standard Operating Procedures
v/v	Volume per volume
VST	Virus-specific T cells

Term	Definition
Chain of Custody	A process that captures drug product handoff across various entities to ensure proper handling, including storage and temperature conditions
Chain of Identity	A process used to link a specific drug product to a specific patient from enrollment to treatment
Chain of Identity Number	A unique number, used in concert with patient identifiers, to link a specific treatment to a specific patient throughout the process
Dewar	A specialized vacuum flask used to hold liquids at well below ambient temperature. For this study, a dewar may be used to store/transport cryogens, whose boiling points are much lower than room temperature, this is the liquid nitrogen containment compartment inside of the LN2 Shipper.
Expiry Date	The date before which the drug product and/or placebo must be administered to patients
JUDI	AGMednet's "JUDI Adjudication" is a cloud-based platform built to manage end-to-end HLA adjudication workflows.
Manufacturing Lot Number (MFG. #)	A unique identification number assigned to drug product and/or placebo for a single manufacturing run
Patient ID	A unique identification number that is linked to a patient for all study visits/treatments

3 ICON LEGEND

Throughout this manual, the following icons are used to highlight specific aspects of the cell tracking process and/or important steps:

	Distinct identifiers used for patient specific cell product
	Information entered into IRT
	Documentation to send
	Form for site to complete
	Email notifications
	Important Step

4 SYSTEMS USED

The systems referred to throughout this manual are summarized below.

System	Owner	Users	System Used	Process for Obtaining Access	References
FlexAdvantage® IRT	ICON	• Clinical Site • ICON	IRT will be used to screen and randomize patients. IRT will also be used to acknowledge IP and dispense IP.	Access to be provided by ICON during study start up. To add users during the study, please contact your assigned CRA	IRT Site User Reference Manual and Help Desk
Cryoportal	Cryoport	• Azenta US, Inc.(depot) • AlloVir	Cold chain logistics system used to track/manage shipments of IP	Access provided via shipment notification email. See Section 9 of this manual for additional details.	N/A
JUDI	ICON	• Clinical Site • ICON	Submit HLA report and manage end-to-end adjudication workflows	JUDI Manual	JUDI Manual

5 INTRODUCTION AND STUDY OVERVIEW

5.1 Introduction

This Cell Therapy Manual is a reference manual for the Investigator and investigative site staff, including the cell therapy laboratory staff, or pharmacist and pharmacy personnel involved in the use of this investigational product (IP). The following is a guidance of minimum acceptable procedures and does not replace an understanding of, or adherence to, the requirements contained in the approved protocol, applicable regulations, guidelines, good clinical practices, aseptic preparation techniques, or Standard Operating procedures (SOPs) governing this study. Furthermore, this document does not replace cell therapy standards established by accreditation agencies such as Foundation for the Accreditation of Cellular Therapy (FACT), the AABB (formerly known as American Association of Blood Banks).

The purpose of this Cell Therapy Manual is to provide guidance by outlining minimally acceptable standards for the request, receipt, storage, preparation, dispensation, administration, return/destruction, and IP accountability.

The Cell Therapy Manual will be updated and revised as needed. The most recent approved version will take precedence over any previous version(s).

5.2 Study Information

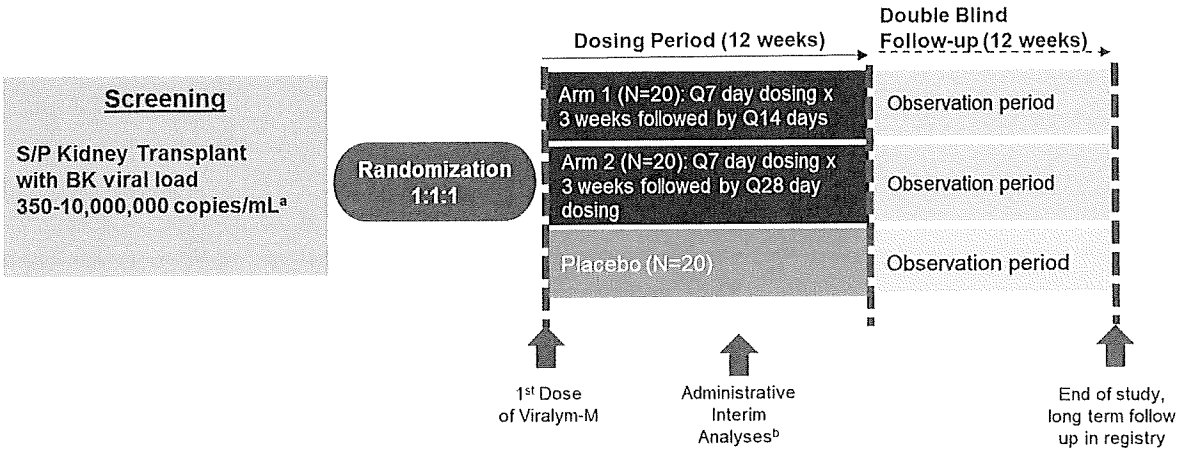
P-105-201 is a Phase 2 multicenter, randomized, double-blind, placebo-controlled, multiple dosing interval, 2-period study of the safety, tolerability, and effectiveness of adoptively transferred posoleucel (ALVR105) multivirus-specific T cells in kidney transplant recipients with either high or low levels of BK viremia.

Patients will receive 4 x 10^7 posoleucel (PSL) cells (or placebo). Cryopreservation media (without cells) will serve as the placebo and will be identical in volume and appearance upon administration. All infusions will be administered IV (via peripheral or central line) over approximately 5 minutes as a slow push.

Patients will receive the same volume for injection for all study treatment infusions (Arm 1: Q7 days dosing for 3 weeks followed by Q14 days dosing for a total of up to 12 weeks, Arm 2: Q7 days dosing for 3 weeks followed by Q28 days for a total of up to 12 weeks. Placebo will be administered 14 days after the 3rd infusion, and then Q28 days for a total of up to 12 weeks, Arm 3: Placebo administered Q7 days for 3 weeks followed by Q14 days for a total of up to 12 weeks).

A study schematic is displayed in Figure 1.

Figure 1: Study Schematic



Doses here refer to doses of T cells/placebo. For example, in Arm 2, 4×10^7 ALVR105 cells once weekly for 3 weeks followed by once every 28 days for the remaining 12-week dosing period. Placebo will be given 14 days after the 3rd infusion and then every 28 days over the next 12 weeks.

6 INVESTIGATIONAL PRODUCT DESCRIPTION

6.1 Composition

Investigational product refers to PSL or placebo. PSL is a biological product consisting of PSL cells (third-party multivirus-specific T cells with specificity for BK virus [BKV], cytomegalovirus [CMV], human herpes virus 6 [HHV-6], Epstein-Barr virus [EBV], and adenovirus [AdV] in cryopreservation media.

PSL will be supplied in 6.0 mL capacity AT-Closed Vials® (Aseptic Technologies) (formerly referred to as a cryovial) at a concentration of 1×10^7 virus-specific T cells (VSTs)/mL in a volume of approximately 2.5 mL. PSL will be frozen in a cryopreservation media containing 50% volume per volume (v/v) of 25% human serum albumin, 40% (v/v) Hanks balanced salt solution, and 10% (v/v) dimethyl sulfoxide.

Cryopreservation media (without cells) will serve as the placebo. Placebo will be provided in the same 6.0 mL capacity AT-Closed Vials as PSL and will be identical to PSL in volume and appearance.

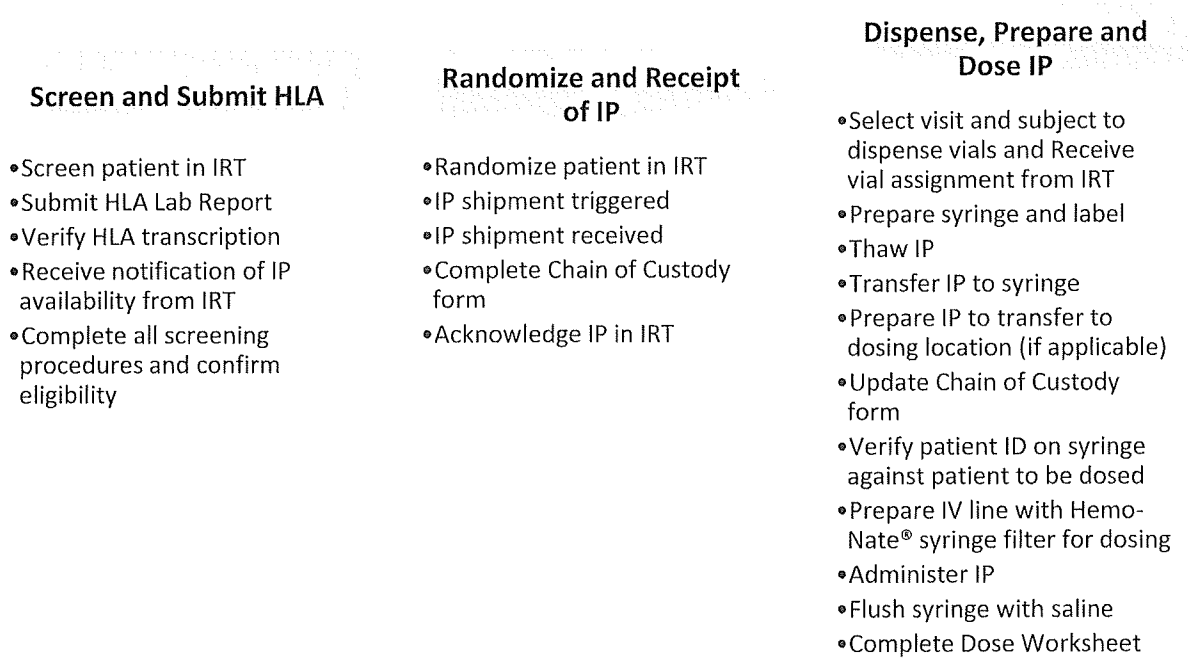
6.2 Human Leukocyte Antigen (HLA) Matching

CytoMatch™ (AlloVir, Inc.), a validated computer algorithm, will be used to select the particular PSL cell line for an individual patient based on the overall level of HLA match between (a) the cell lines within the bank and the kidney transplant donor and (b)if the patient is a transplant recipient, the cell lines within the bank and the transplant donor(s).

6.3 Overview of IP Process

A high-level overview of the steps the clinical site will perform to receive IP, prepare the IP, and administer the IP to a study participant is displayed in Figure 2.

Figure 2: IP Process



Notes:
Randomization can be done by BLINDED site staff (Principal Investigator, Sub-Investigator and Coordinator).

Receipt of IP, Dispensing and Preparing IP done by UNBLINDED site staff.

Dose IP (infusion of IP) is done by BLINDED site staff.

7 PACKAGING AND LABELING

The packaging and labeling of the IP are outlined in the following sections.

PSL / placebo is supplied to sites in AT-Closed Vials packed in a cryobox shipped in an LN2 shipper.

7.1 Packaging

Aseptic Technologies, AT-Closed Vial®

IP will be supplied in 6.0 mL AT-Closed Vials at a concentration of 1×10^7 cells/mL in a volume of approximately 2.5 mL.

The vials are cryogenic, self-standing and capped with a snap-fit cap that protects the septum.

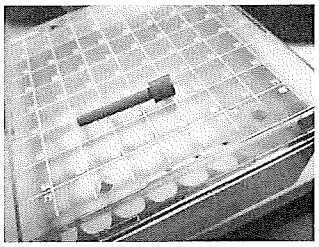
AT-Closed Vial®	6.0 mL
Height	40.3 mm including the cap, (-1 mm with cap removed)
External vial diameter	25.0 mm
Maximum volume filled	7.6 mL

Cryobox

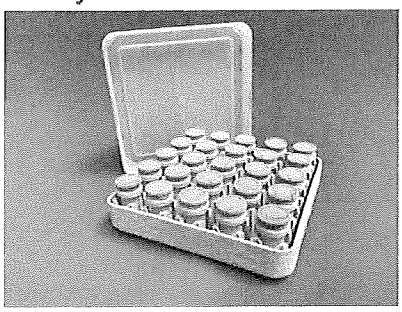
Dimensions: L 133 × W 133 × H 57 mm

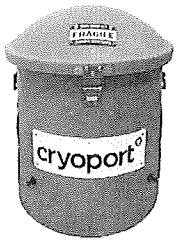
Maximum Capacity: 25 vials

Note: The cryobox can be used to store IP at the site; return to Depot is not required.



AT-CryoBox™



LN2 Shipper High Volume LN2 shipper will have a rack holding multiple cryoboxes. Each cryobox contains the Investigational Product for only one patient. If a site is expected to receive multiple patients' IP in a single day, the LN2 shipper may contain multiple cryoboxes (shipments) for multiple patients. Carefully check the Azenta BioInventory Package Manifest. The Cryoport LN2 shipper pictured here is representative of the LN2 shippers that will be used.	

7.2 Labeling

The IP will be labeled by the manufacturer as pictured below.

Allovir, Inc. LB-0207
ALVR105 or Placebo Dispersion for Infusion
2.5 mL / Vial; $1.0x10^7$ cells/mL
For Intravenous Administration Only
Lot Number: 126-YY-0XXXL
DOM: 19JUN20 Vial No. 001
Store in Vapor Phase Liquid Nitrogen ≤ -150°C
Caution: New Drug-Limited by Federal Law to Investigational Use

The secondary labels will be provided with the shipment of the IP. A secondary label will be provided for each lot included in the shipment. The secondary labels may contain additional information to be completed by the site.

ALVR105 or Placebo Dispersion for Infusion cryopreserved in: 50% (v/v) of 25% HSA, 40% (v/v) of HBSS, and 10% (v/v) DMSO. IND#: 15092

Contents: 2.5 mL / Vial; 1.0 x10^7 cells/mL

Lot #: 126-YY-0XXXL

For intravenous administration only. Store in Vapor Phase Liquid Nitrogen ≤ -150°C

See Cell Therapy Manual for Additional Product Information for Use and Expiry.

DO NOT IRRADIATE

DO NOT USE LEUKO-REDUCTION FILTER

Manufactured By:
Cognate BioServices Inc. for AlloVir Inc.,
4600 E. Shelby Dr. #108 Memphis, TN 38118
Phone #: 936-662-9626
Caution: New Drug-Limited by Federal Law to Investigational Use

The expiration date of each vial will be listed on the IRT Shipment Request Form (Appendix E) which will be included in the IP shipment documentation sent to the site.

8 SHIPMENT AND HANDLING PROCEDURES

Prior to site activation, the site will provide the shipping address, contact information, and times site staff are available to receive IP from the courier. If there are any changes to this information, please contact the assigned CRA. The site will receive 2 planned shipments per patient randomized into the study:

1. The first shipment of 10 vials will occur after randomization of a patient in IRT by the site and will include PSL (best matching cell line available) / placebo depending on the arm to which the patient has been randomized into. Initiation of the first shipment **requires action by the site** as detailed below.

2. The second shipment of 6 vials (PSL / placebo) will occur after the site confirms if the patient will be administered IP at Week 6 in the IRT and will include PSL (best matching cell line available) / placebo depending on the treatment arm the patient was randomized to. Initiation of the second shipment **does not require additional action by the site**.

The receipt and handling procedures for Shipment 1 and 2 are identical.

P-105-201 Shipment Breakdown:

Table 1: IP Shipment – Arm 1

Number of Vials	IP TYPE
10 vials	PSL
6 vials	PSL
Total: 16 vials (2 vials infused per dosing visit in the treatment phase Day 1 through Week 12)	

Table 2: IP Shipment – Arm 2

Number of Vials	IP TYPE
10 vials	8 vials of PSL and 2 vials of Placebo
6 vials	2 vials of PSL and 4 vials of Placebo
Total: 16 vials (2 vials infused per dosing visit in the treatment phase Day 1 through Week 12)	

Table 3: IP Shipment – Arm 3

Number of Vials	IP TYPE
10 vials	Placebo
6 vials	Placebo
Total: 16 vials (2 vials infused per dosing visit in the treatment phase Day 1 through Week 12)	

8.1 First Shipment of IP (per patient randomized)

During patient screening, the clinical site completes "Screen a Patient" in the IRT and will upload the annotated, redacted HLA source documents (i.e., intermediate or high-resolution HLA report) for the patient and the patient's kidney transplant donor to the JUDI database. JUDI will notify the site when the transcription of the HLA information from the HLA source documents is available for the site to verify. The site will login to JUDI and verify the HLA transcription within JUDI. An IRT notification will be emailed to the site notifying an available cell line (patient lot number verified) is present.

Please refer to the JUDI Manual for detailed instructions.

Shipment of the IP to the investigative site's cell therapy laboratory/or study pharmacy will occur only after a patient has been randomized in the IRT as noted above.

The procedure for reporting HLA type, shipping and receiving IP, and communication and documentation requirements are listed below:

Upon screening a potential patient, the clinical site reports the following information through IRT using the action "Screen a Patient":

- Patient's sex
- Year of patient's birth
- Visit date

The CRO and AlloVir study team is notified when the site completes this action. The IRT assigns the patient ID.

The site will print the transaction confirmation from IRT and file it in the subject documentation.

↓

Clinical site uploads annotated, redacted electronic copy of the HLA source document for the patient and patient's **kidney** donor to the JUDI system.

↓

The HLA report must be submitted in JUDI as soon as possible after screening. Please reference the JUDI manual for additional detail.

Site receives an email notification from the IRT of the upcoming shipment of IP. If PSL match is not identified in the bank, the site will receive an email notification from the IRT indicating that this patient is not eligible for participation in the study. The clinical site should screen fail the subject in IRT if the patient is not eligible.

Site receives email notification from Cryoport which includes the following information:

- Cryoport Shipment Order Number and Live View link for shipment tracking

  Live View link can be used to view the shipper's location and temperature

- Anticipated delivery date and time of shipment; generally expected within 48 hours from the time the shipment request was received by the depot

- Anticipated pickup date and time of the empty LN2 shipper

If there are delays in the shipment of IP, the site will receive an email notification from Cryoport. In the unlikely event a shipment delay prohibits the site from receiving the delivery, follow the Issue Reporting Instructions found in Section 10 Issue Reporting Instructions.

8.2 Second Shipment of IP (per patient randomized)

The second shipment request of IP is automatically initiated after the clinical site confirms a patient will be infused IP at Week 6 in the IRT.

Note: In general, the first shipment IP will be delivered to your site within two business days of randomizing an eligible patient (trigger for first shipment). It is advised that sites complete the above actions within the morning hours, preferably by 9:00 AM local time for best chance to receive the IP the following day. The second shipment request is initiated when the site confirms a patient will receive an IP infusion at Week 6 (trigger for second shipment).

9 RECEIPT, HANDLING, UNPACKING PROCEDURES

9.1 Receipt of Product at the Investigative Site

The site will receive an email notification from Cryoport when the IP is delivered. The Temperature Stability Report (Appendix A) will also be emailed to and is to be filed by the site. The Cryoport Live View Link provided in the initial order notification email can be used to view the LN2 shipper's location and temperature.

The site personnel receiving the LN2 shipper will inspect the LN2 shipper and handle AT-Closed Vials as described in the Section 9.2 Inspection of Shipment. Prior to unpacking the shipper, the site staff will record the lot and vial numbers from the IRT shipment request on the Chain of Custody form (Appendix B) and file the documentation per site SOPs. The site reviews AT-Closed Vial labels and checks received lot and vial numbers against the IRT shipment request form.

Upon completion of inspection, unpacking, and storage at the site (see inspection instructions below), the site reports the following information in the IRT:

- Order ID
- Shipment condition at receipt
- Date Received and Date and Time of Removal of Cell Product from the LN2 Shipper (maybe added in the comments field)
- At the conclusion of the action, site will print the transaction confirmation from the IRT and file it.

If you have unacknowledged shipments at your site, you may be blocked from performing certain actions within the IRT.

9.2 Inspection of Shipment

External Inspection of the LN2 Shipper

- Carefully transport the LN2 shipper to unpacking area for inspection. The shipper must always be maintained in an upright position.
- Inspect the LN2 shipper for any damage or disruption to the seal. Ensure that the zip tie was intact at the time of delivery and document on Chain of Custody form (Appendix B).

Courier Shipment Label

- Inspect the courier shipment label that arrived with the LN2 shipper. Confirm the courier shipment label arriving with the LN2 shipper matches courier shipment label received in the Cryoport email notification.

Temperature

- Review the Cryoport Temperature Stability Report (Appendix A) to confirm there were no temperature excursions during transit. If the report notes a temperature excursion during transit, follow the Issue Reporting instructions in Section 10 Issue Reporting instructions.
- The Cryoport Live View Link provided in the initial order notification email can be used to view the shipper's location and temperature.

9.3 Handling the LN2 Shipper

- The LN2 shipper will arrive with black rubber or metal latches zip-tied; use caution when cutting and removing the zip ties.
- Remove the old shipping pouch and discard the Leg 2 (site delivery) Shipping Airway Bill.
- The LN2 shipper will be stored in a safe location.
- The frozen IP should be unloaded same day of the arrival of the LN2 shipper.
- Empty LN2 shipper should be stored in an area with adequate cell signal; avoid areas like basement rooms or refrigerators where data transmission may be blocked.
- The pouch labeled "DOCUMENTS ENCLOSED" with a check list is adhered to the inner surface of the shipper mushroom lid on the right

Plastic Pouches adhered to the inner surface of the shipper mushroom enclosure lid.

The clear shipping pouch on the left contains the unloading instructions and EMPTY label. The shipping pouch labeled "Documents Enclosed" contains commodity shipping labels, shipper certificate, packaging list, four (4) zip ties, and loading instructions.

Three transparent hanging sleeves are attached to the handle of the dewar inside the shipper enclosure. All large sleeves are reusable and should be returned with the shipper to Cryoport. Return shipping instructions are located below under *Returning the Shipper to Cryoport.*

and will contain four (4) zip ties.

- An unlabeled pouch adhered to the inner surface of the shipper mushroom lid on the left will contain unloading instructions and the "EMPTY" label.

The Leg 2 (site delivery) sleeve contains the Leg 2 airway bill and a new shipping pouch to attach to the shipper for the next shipment. The Leg 3 (return shipment) sleeve contains a sheet warning that the documents contained are intended for shipper return to Cryoport, the Leg 3 airway bill, and a new shipping pouch. An unlabeled sleeve may be included to hold additional Cryoport provided accessories.

9.4 Unpacking and Storage of ALVR105/Placebo

Following delivery and inspection of the IP, the site should transfer the product rapidly from the LN2 shipper to a vapor phase LN2 freezer with continuous temperature monitoring until the day of infusion (please refer to handling instructions below).

- It is the responsibility of the site to ensure Investigational Product (IP), PSL/ placebo is stored at ≤ -150°C and to monitor the temperature of the storage conditions.
- Please refer to Figure 3 for a visual representation of the steps required to unpack the LN2 shipper.
- If a temperature excursion occurs, follow the Section 10 Issue Reporting instructions10.

Take all necessary measures to avoid prolonged exposure of the cryopreserved vials to conditions outside of the LN2 shipper and/or vapor phase freezer. It is critical to minimize the time the IP is handled outside the LN2 shipper to no more than one (1) minute.

- Unlatch the LN2 shipper in one of two ways:
  - If the shipper has Silver Metal Latches, unlock the latches by turning the key to the left. The latch will unhook from the top of the metal hardware.
  - If the shipper has Black Rubber Latches, pull the black handle down and away from the shipper.
- Open the lid to expose the dewar.
- Remove the vapor plug to retrieve and remove the Subject-labeled IP packaging from the dewar.
- Replace the vapor plug and allow it to settle down completely.
- Do not tamper with the Smartpak II® Conditioning Monitoring system located at the top of the vapor plug. Cryoport will continue to monitor the GPS location until Leg 3 delivery is completed, and the collected temperature information for Leg 2 will automatically be compiled and sent to all parties once available.

- Visual inspection of the IP should be conducted as close to the LN2 freezer where the IP will be stored as possible.
- The vials must remain upright at all times.
- Carefully remove the vials from the LN2 shipper by taking out the Cryobox from the metal rack and inspecting the Cryobox and vials for damage.
- Review vial labels and check received lot and vial identification (ID) numbers on the Chain of Custody form.
- Place the IP back into the LN2 shipper or place in LN2 freezer at the site as rapidly as possible.
- Complete shipment receipt sections of the Chain of Custody form (Appendix B) and file.

If any issues are found during inspection and handling, follow the Section 10 Issue Reporting Instructions.

Figure 3: Steps outlining unpacking of the LN2 shipper

9.4.1 Documents

- The following documents will be included:
  - Azenta BioInventory Package Manifest (Appendix D)
  - IRT shipment request (Appendix E)
  - Secondary label(s) (one per vial)
  - Shipper return labels
  - Safety Data Sheet (SDS)
  - Certificates of Conformance (for both ALVR105/placebo)
- The site will complete and file all documents received with the IP shipment.

9.4.2 Returning the Shipper to Cryoport

- After unloading the IP, the LN2 shipper must be returned to the respective Cryoport facility of origin the day after receipt, as prearranged by ICON and Cryoport on the Cryoportal®.
- Ensure the metal rack has been placed back into the LN2 shipper for return.
- Remove the Leg 2 Airway Bill, clean shipping pouch and "EMPTY" adhesive label from the hanging sleeve labeled "LEG 3" attached to the handle of the dewar inside the enclosure.

- Attach the clean shipping pouch and the Leg 3 Airway Bill to the metal rectangle on the side of the shipper where the original Leg 2 shipping documents were, as described in Section 9.3.
- Unpeel/remove any Final Product labels from the side of the shipper as cleanly as possible.
- The adhesive "EMPTY" label should be removed from its backing and fully pasted onto the metal diamond on the side of the shipper.
- Secure the LN2 shipper with two provided zip ties on each of the latches.
  - Silver Metal Latch
    - Insert the zip tie down through the lid catch.
    - Thread the zip tie through the body latch spring loop.
    - Thread the zip tie up through the body latch turn-buckle hole.
    - Bring the zip tie end up to the buckle.
    - Insert zip tie through the lid buckle and tighten.
  - Black Rubber Latch
    - Insert the zip tie through one of the holes on the metal latch hardware.
    - Thread the zip tie horizontally through the hole on the other side of the metal hardware.
    - Insert zip tie through the lid buckle and tighten.
- The empty LN2 shipper may be stored at ambient temperature until ready for pickup.
- Storage location should be in a room-temperature area; the condition monitoring system is sensitive to temperatures refrigerated and lower.

If the site has any issues regarding return of the empty LN2 shipper (including changes to the pickup date, time or location) the site should contact Cryoport and the CRA.

10 ISSUE REPORTING

Investigative product must be stored in vapor phase temperature conditions (≤ -150°C) prior to thaw for dosing. Temperature excursions that occur at the site will be evaluated on a case-by-case basis by AlloVir. When a temperature excursion (i.e., temperature > -150°C) occurs, the site will follow the Issue Reporting instructions below.

Urgent issues during dose preparation or dosing that require immediate attention will be reported by the site to the AlloVir Medical Lead by phone. The unblinded Clinical Trial Manager should also be contacted. See Section 1 for more details.

Throughout the study, the site will report issues that arise by completing the Issue Reporting Form (Appendix F) and submitting form via email to the Unblinded, if applicable CRA or another individual as per study specific instructions.

Issues reported on the form will include, but not be limited to, the following:

- Issues with IP
- Reconciliation/destruction
- Temperature excursions (on site or in transit)

As noted above, the site is to report urgent issues by phone immediately and submit the Issue Reporting Form.

Completed Issue Reporting Forms should be filed in the Investigator Site File (ISF).

11 RANDOMIZATION AND IP ASSIGNMENT

Trained site personnel access the IRT initially to register a patient. Treatment assignments for patients are determined as described in the protocol. Patients are randomized via IRT according to the protocol. The IRT reserves IP vials during screening and a subset of the reserved vials are assigned by the IRT at the time of randomization. The IRT vial assignment confirmation should be printed and filed.

Once a patient is screened in the IRT by the site, a patient ID is assigned. As described in Section 8 , ICON operates CytoMatch and the IRT so that specific vials of IP are reserved for the patient and shipped to the site from the local US depot, Azenta.

11.1 Randomizing a Patient and Assigning IP Vials for the First Dose

Day 1 procedures must be performed within 96 hours of randomization and prior to study treatment administration.

At the time of randomization, trained site personnel access the IRT to randomize the patient. The IRT randomization transaction confirmation is to be printed out and filed in the ISF.

Randomizing a Patient

Site selects the patient and goes to the randomization tab and clicks "Randomize a Patient" to complete the transaction.

Completing this action will randomize the patient in the IRT and will enable the unblinded cell therapy lab/pharmacy/designee site staff to assign the IP vials for the first dose.

Assigning Vials for First Dose

Unblinded cell therapy lab/pharmacy/designee site staff selects Randomize and assigns the IP vials for the first dose by selecting the following:

- Patient ID
- Visit ID

The transaction confirmation will list the expiration dates of the vials assigned.

At the conclusion of the action, sites will print the transaction confirmation from the IRT in duplicate, for filing and for reference during IP preparation. Repeat these steps for assigning vials at any infusion visit.

The CRO and AlloVir study team is notified when the site completes this action.

The site will receive 16 vials of IP for each study patient with a first shipment of 10 vials (covering through week 6) and a second shipment of 6 vials (covering through week 12) if needed. It is imperative to select only the specific vials allocated by the IRT for each specific patient to ensure the appropriate vials are prepared.

Completion of Randomization in the IRT will automatically generate shipment of IP to the clinical site. See Section 8.2 for additional detail.

NOTE: Please refer to the IRT Site User Reference Guide for detailed instructions when navigating the IRT system.

12 DOSE PREPARATION AND EQUIPMENT

Preparation of the IP should be performed per the instructions in the Cell Therapy Manual and in alignment with the site's SOPs.

12.1 Equipment and Supplies

The supplies listed will be utilized to support this study:

Equipment provided by CRO/AlloVir:

- 5 mL Luer lock syringes
- AT-Adapt™ (single-use needleless connection device)
- Hemo-Nate® syringe filter (referred to as "Hemo-Nate filter" below)
- Syringe caps
- 3-way stopcock
- Syringe labels (please see Syringe Label Template Appendix C)
- Upon request, Cryopod (dry shipper for transporting from LN2 freezer to location of thaw) with temperature monitoring

Equipment provided by site:

- Infusion tubing for IV injection
- Dry-Block heater or water bath
- Bag of sterile normal saline (e.g., 50 or 100 mL, but any volume is acceptable) for priming of IV line and flushing of line and syringe
- 5 or 10 mL normal saline flush for priming the Hemo-Nate filter

12.2 Prohibited Equipment/Supplies

The only filter that should be used for the infusion is the Hemo-Nate filter provided by the Sponsor. **No in-line leuko-reduction filters should be placed between the syringe containing IP and the patient.**

13 CHECKPOINT – PRIOR TO INITIATING THAW – OVERVIEW OF PROCESS

Prior to initiating thaw, it is important to coordinate the timing of IP thaw and infusion with the patient's nurse. Study treatment must be infused within 30 minutes of completion of thawing. The person designated to thaw the cells should contact and receive confirmation from the clinical team that the patient is cleared and ready to receive treatment and the IP has been assigned in the IRT.

Critical Checks
• Patient is in the infusion location and ready to receive the infusion
• Peripheral or central IV access is in place
• Hemo-Nate filter has been primed (if being done in a biological safety cabinet) or ready to be primed (if being done at bedside)
• IV lines have been primed

The infusion of IP must be completed within 30 minutes following completion of the thawing of the designated vial(s) of IP. To ensure this timeframe, all documentation and labels should be prepared prior to removal of IP from vapor phase LN2 storage. If the Hemo-Nate filter is to be primed in a biological safety cabinet, this should also be done prior to thawing IP. Investigative product should be thawed at a satellite location close to the infusion location when feasible.

13.1 Preparation Instructions for the Infusion

1. Upon receiving confirmation from the clinical team, retrieve the Dose Worksheet (Appendix G) and the randomization or dose transaction IRT transaction confirmation (see instructions in Section 11 of this manual).
   a. Upon randomization/dose transaction, IRT will assign the IP vials to be administered and these will be listed on the IRT transaction confirmation with the expiration date of the vial.
2. Retrieve the appropriate secondary IP labels.
3. Review the IRT transaction confirmation and ensure the assigned vials are not expired. (If a vial is expired, do not proceed with the thaw and infusion, and follow the Issue Reporting instructions in Section 10 of this manual.)
4. Transcribe the patient ID and vial number from the IRT transaction confirmation onto the printed syringe label.

5. Remove the 2 designated IP vials from vapor phase LN2 storage with protective equipment as indicated by the site SOP. Record the time of removal from vapor phase LN2 on the Dose Worksheet (Appendix G).
6. Proceed with the thawing IP immediately as detailed in Section 14.

13.1.1 Emergency Recovery Procedure

If the IP vial is observed to be cracked when removed from storage, or if cracks or leaks occur during thawing or preparation, **immediately notify the Investigator or Sub-Investigator and follow the directions in Section 1 of this manual for "urgent issues during dose preparation or dosing that require immediate attention."** The Investigator/Sub-Investigator and Sponsor will determine whether to use or discard the IP.

14 THAWING OF IP

There are **two options** for the location of thawing and preparing IP (Figure 4). The site should select an option that will ensure that the 30-minute time limit between the end of thawing of IP and the end of the infusion of IP will be met.

Option 1: Thaw IP at the patient's bedside or in a nearby area.

Place frozen vials in an LN2 dewar for transport to ensure that they are held at the correct specified temperature prior to thaw. Transport the IP to the patient bedside location or preparation room on the patient ward or in the clinic or infusion center. Proceed to the thaw and preparation steps as described below.

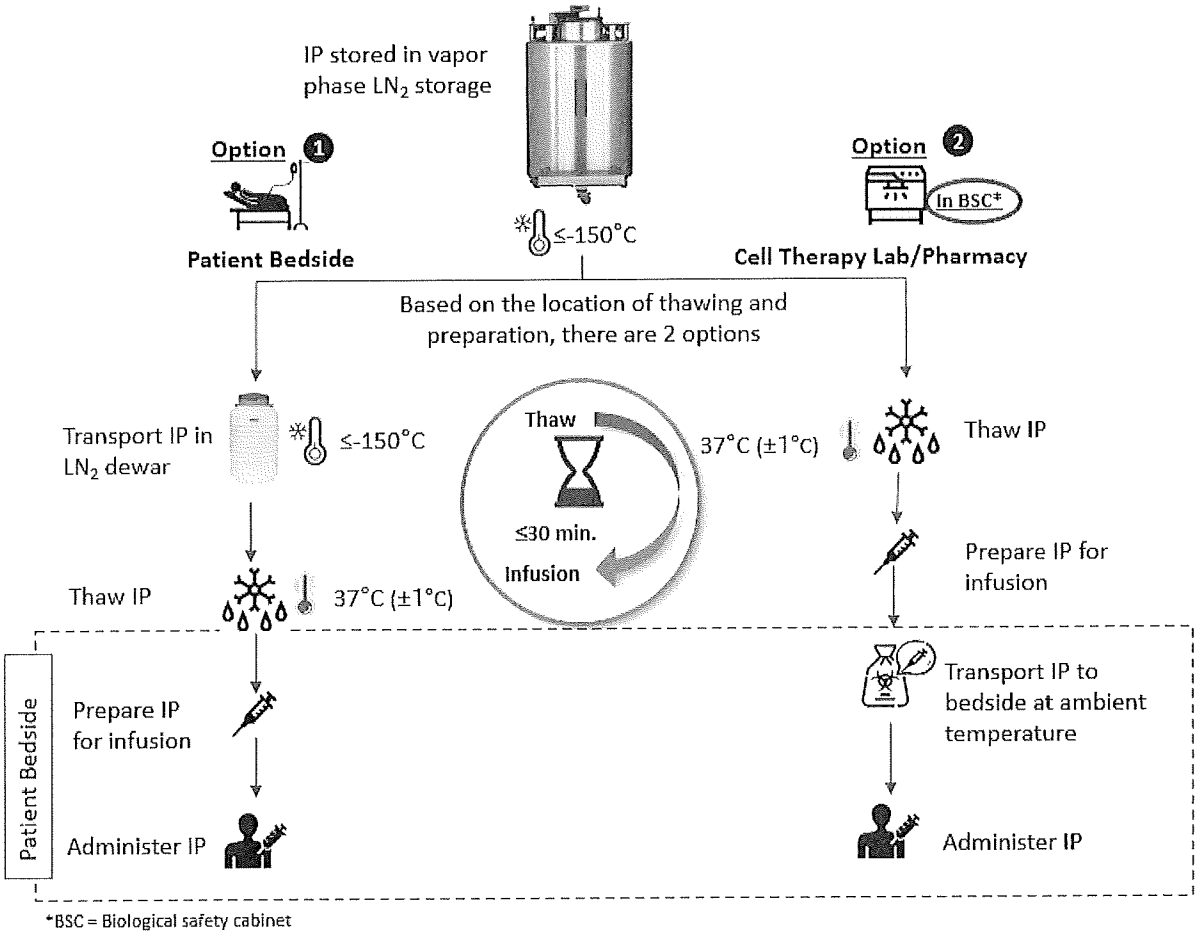
Option 2: Thaw IP in a Biological Safety Cabinet in the Cell Therapy Laboratory or Pharmacy (or a similar location).

Proceed to the thaw and preparation steps as described below. Then transport the IP to the patient's bedside: Place the syringe in a biohazard bag or equivalent, then place the bag into a suitable transport container at ambient temperature per site SOPs. Transport the container to the infusion site

The infusion of IP must be completed within 30 minutes following completion of the thawing of the designated vial(s) of IP. This does not include the flushes after administration of the IP.

Take all necessary measures to avoid prolonged exposure of the cryopreserved vials to conditions outside of the LN2 shipper and/or vapor phase freezer. It is critical to minimize the time the IP is handled outside the LN2 shipper and/or vapor phase LN2 freezer to no more than one (1) minute.

Figure 4: Storage to Infusion Flowchart



There are **two options** for the location for priming the Hemo-Nate filter, either at the bedside (which is covered in the section on Administration below) or in a biological safety cabinet or similar equipment in the Cell Therapy Laboratory, Pharmacy, or a similar location. When the priming step is done in a biological safety cabinet, it should occur **prior** to thawing the IP.

For sites that prefer to prime the Hemo-Nate filter in a biological safety cabinet, follow the instructions immediately below:

1. Remove the Hemo-Nate filter from its packaging under aseptic conditions (e.g., in a biological safety cabinet; see Section 15 on Preparation of syringe below for additional details on acceptable equipment) and attach a syringe containing sterile normal saline. Prime the Hemo-Nate filter by injecting a minimum of 1 mL of normal saline through the filter, allowing the excess to spill into a container. It is acceptable to prime with a larger volume if using a prefilled syringe (e.g., 5 or 10 mL).
2. Follow the steps for thawing the IP and transfer it to a 5 mL syringe (See Section 15 on Preparation of syringe below for the next steps.

Site personnel must complete the Dose Worksheet (Appendix G) during preparation and dosing of the IP. Complete the Dose Worksheet for each dose prepared and administered to the patient. Also, update the Chain of Custody form (Appendix B) after each administration.

5

This study requires 2 vials per infusion per patient. When thawing both IP vials (for the same patient), thaw both vials at the same time in the same manner.

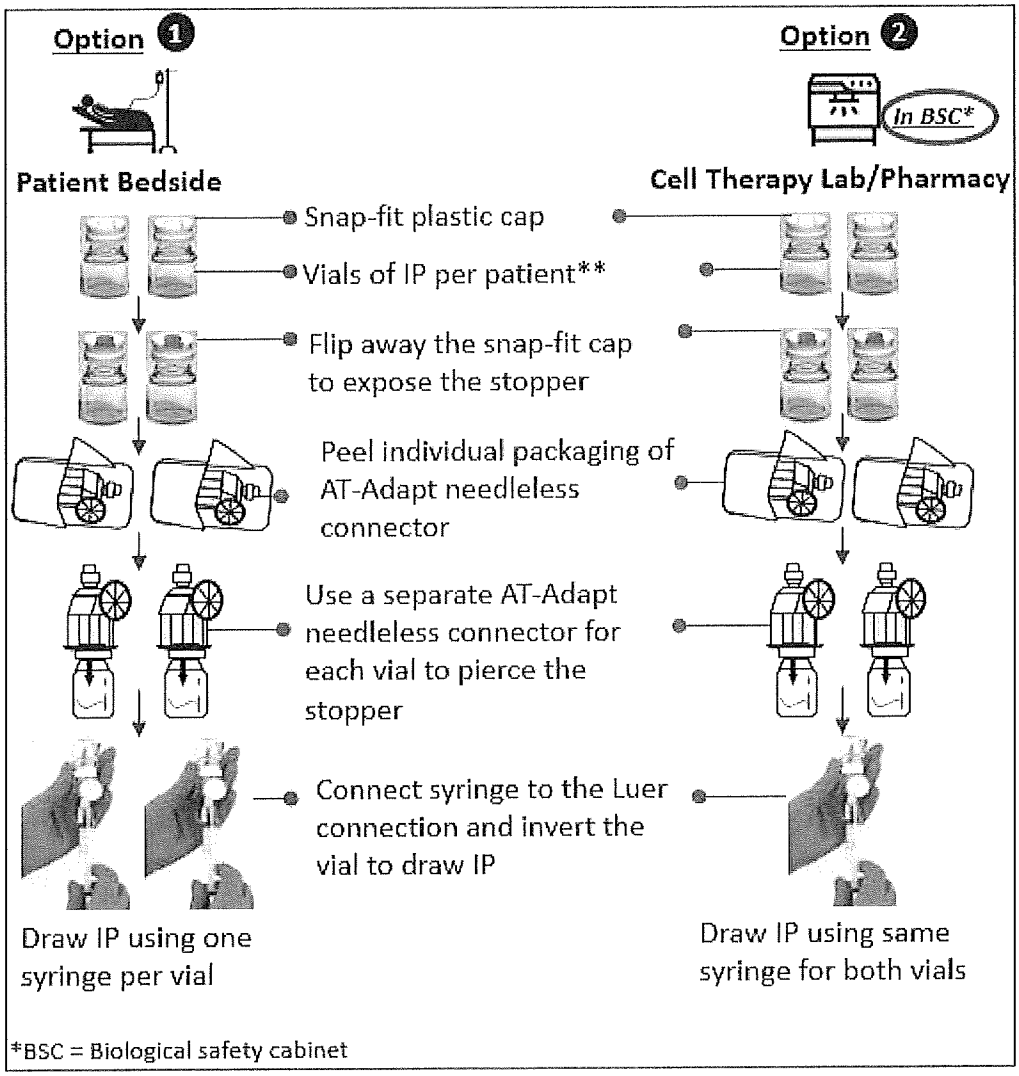
1. Immediately thaw designated vial(s) in a Dry-Block Heater at 37°C (±1°C) per site SOPs. It is also acceptable to thaw vials in a pre-heated 37°C (±1°C) water bath within a sealed bag consistent with clinical site's SOPs. **Do not shake vials in water bath.**

2. Observe the designated vial(s) of IP carefully as the thaw time may vary.

3. The IP can be considered fully thawed when there are no more ice crystals visible inside the vial. At this time, the vial(s) should be removed from the thawing device and thoroughly wiped with an alcohol swab.

4. Record the time of thaw completion for the designated vial(s) on the Dose Worksheet (Appendix G).

15 PREPARATION OF SYRINGE



NOTE: AT-Adapt™ Reminder

When spiking the AT-Closed Vial®; place the AT-Closed Vial® on a flat surface; move the AT-Adapt™ in a downward motion into the vial. Spike should be perpendicular to stopper. Do not insert at an angle. For step-by-step instruction on the use of the AT-Adapt™ please refer to the manufacture's user guide (Appendix H).

Option 1: Preparation of IP at the patient's bedside or in a nearby area

To ensure sterile conditions, use one syringe per IP vial. If there are multiple vials required to complete the full dose, draw the volume indicated for each vial into a separate syringe.

1. Use the AT-Adapt™ needleless collection device to draw the prescribed dose into each labeled 5 mL Luer lock syringe. Use a new AT-Adapt™ needleless collection device for each individual syringe.

Option 2: Preparation in a Biological Safety Cabinet in the Cell Therapy Laboratory or Pharmacy

1. Use the AT-Adapt™ needleless collection device for AT-Closed Vials to draw the appropriate dose into a labeled 5 mL Luer lock syringe. Use a new AT-Adapt™ needleless collection device for each individual vial.

2. Aseptically withdraw IP under sterile conditions from each vial in a class II biological safety cabinet or class II (or ISO class 5) laminar flow hood or more stringent equipment (e.g., class III biological safety cabinet or aseptic isolator) with a blunt 16-gauge needle attached to a labelled 5 mL Luer lock syringe.

   - Each IP vial will contain approximately 2.5 mL of IP. After withdrawing the specified 2 mL from each vial, there should be residual volume left.

   - **IMPORTANT**: Since two IP vials are required per infusion per patient, draw 2 mL from each vial into a single 5 mL syringe (rather than into two separate syringes).

   - Dispose of used vials as biohazard waste in accordance with local governing regulations and clinical site SOPs.

3. **If your site plans to prime the Hemo-Nate filter in the biological safety cabinet,** attach the primed Hemo-Nate filter to the syringe containing the IP and place the sterile syringe cap on the exposed end of the filter. Make sure that all three components are securely attached.

4. **If your site plans to prime the Hemo-Nate filter at the bedside**, cap the syringe with a sterile cap.

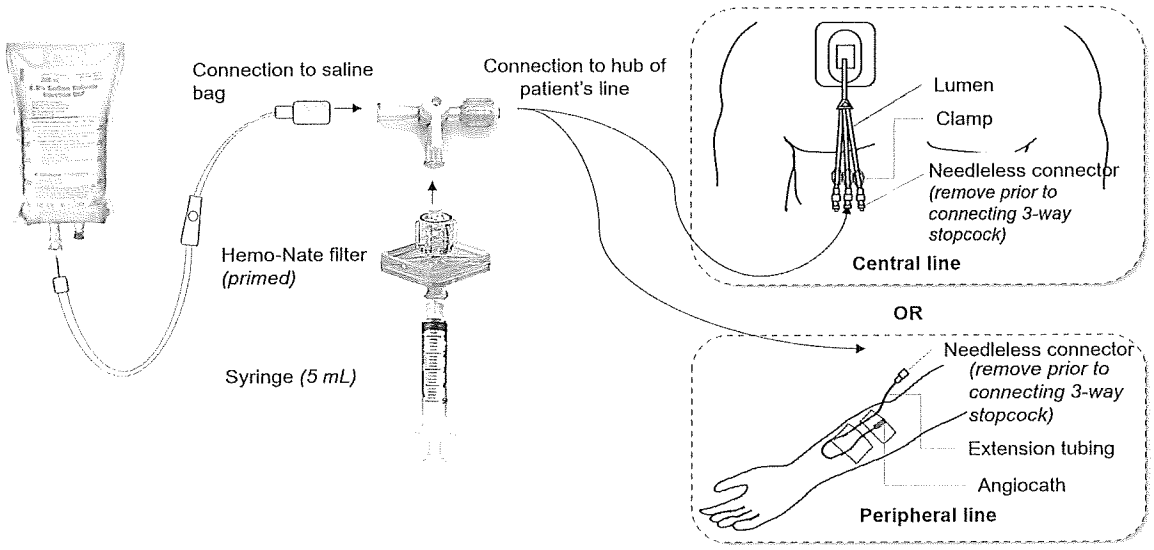
5. Affix the prepared label to the 5 mL Luer lock syringe.

6. Place the syringe (with the primed Hemo-Nate filter attached if priming was done in the biological safety cabinet) in a biohazard bag or equivalent, then place the bag into a suitable transport container per site SOPs.

7. Transport the container at ambient temperature to the infusion site.

16 ADMINISTRATION OF IP

Figure 6: Set-Up for IP Administration



The IP will be administered by the investigative site personnel as outlined below and per institutional guidelines. Patient safety monitoring during the administration should follow institutional guidelines.

16.1 Premedication

Premedication is not required, except for patients with a prior history of reaction to blood products who will receive premedication with diphenhydramine 0.25 to 0.5 mg/kg IV or orally (maximum dose 25 mg) or a different antihistamine preferred by the study site and/or acetaminophen (paracetamol) 5 to 10 mg/kg IV or orally (maximum dose 1000 mg) prior to study treatment administration. **Premedication with corticosteroids is prohibited**. Any premedication required by a patient will be provided by the site. Any premedication administered to the patient should be recorded in the patient's concomitant medication log.

16.2 Administration Instructions

The IP infusion must be completed within 30 minutes following completion of the thawing of the designated vial(s) of IP. This does not include the flushes after administration of the IP.

Site personnel complete the Dose Worksheet (Appendix G) during preparation and dosing of the IP. Complete the Dose Worksheet for each dose prepared and administered to the patient.

Site personnel to update the Chain of Custody form (Appendix B) after administration of IP.

1. Stop all other infusions prior to the administration of IP.

2. Obtain baseline vital signs prior to the infusion.

3. A bag of normal saline (e.g., 50 or 100 mL, but any volume is acceptable) should be attached to the patient's IV tubing for use prior to and after IP administration.

4. Remove the needleless connector (e.g., Clave) from the central line lumen or peripheral IV that will be used for the infusion.

5. Connect the 3-way stopcock directly to the patient's IV line.

6. **If your site plans to prime the Hemo-Nate filter at the bedside**, remove the Hemo-Nate filter from its packaging and attach a syringe containing sterile normal saline to it. It is acceptable to use whatever volume of normal saline is available (eg, 5 or 10 mL). Prime the Hemo-Nate filter by injecting a minimum of 1 mL of normal saline through the filter (allowing the excess to spill into a sink or container). Leave normal saline flush syringe attached to filter.

7. Connect the primed Hemo-Nate filter to the 3-way stopcock.

8. **Only use the Hemo-Nate filter provided. Do not use a leuko-reduction filter**.

9. Take the Luer-locking syringe containing IP and review the information on the syringe label(s). Confirm that the patient ID listed on the syringe label(s) matches the ID of the patient intended to receive the infusion.

10. Remove the syringe cap from the Hemo-Nate filter (which will have the IP-containing syringe still attached to the other side) and attach the exposed end of the filter to the 3-way stopcock.

11. Remove the normal saline flush syringe from the 3-way stopcock, remove the syringe cap from the first syringe containing the IP, and attach the syringe containing the IP to the filter that has been attached to the 3-way stopcock. **However, if your site plans to prime the Hemo-Nate filter in the biological safety cabinet**, it will arrive at the bedside already attached to the syringe containing IP. In this scenario, remove the syringe cap from the Hemo-Nate filter (which will have the IP-containing syringe still attached to the other side) and attach the exposed end of the filter to the 3-way stopcock.

12. Administer IP as a slow IV push. The total time for the IV push should be approximately 5 minutes.

13. Following the IP infusion, turn the 3-way stopcock and aspirate 5 mL of normal saline from the IV bag into the syringe used to administer the IP and flush it into the patient **as a slow IV push**. Perform this procedure twice. The Hemo-Nate filter and the syringe used to administer IP must remain attached during the saline flushes. Do not use separate (new) syringes for the saline flushes as these flushes are intended to collect residual IP from the syringe that was used to administer the IP. IV extension tubing should be

avoided whenever possible. If extension tubing is necessary for use with a peripheral IV, increase the flush volume as needed to ensure that the entire dose of IP is administered.

14. Document the start time and stop time that the IP infusion was completed (the time *before* the final saline flushes were administered).

15. Once the IP infusion is complete, dispose of the syringe as biohazard waste in accordance with local governing regulations and clinical site SOPs.

16. Remove the 3-way stopcock and place a new needleless connector, if applicable, on the end of the central line lumen or peripheral IV.

In the event that the entire dose is not administered, the reason(s) for not administering the entire dose as well as the volume administered must be documented in the patient's source documentation.

17 POST-ADMINISTRATION

Patients will be monitored according to institutional standards for the administration of cellular therapy and, at a minimum, according to the following requirements:

- Patients in an outpatient setting must remain in the clinic for ≥1 hour after the end of the infusion.
- Patients must remain on continuous pulse oximetry for ≥30 minutes after the end of the infusion.
- Vital signs will be monitored within 30 minutes prior to the infusion, at the end of infusion, and at 15, 30, 45, and 60 (±5) minutes after the end of the infusion.

These monitoring criteria establish the minimum required duration of monitoring for patients in an outpatient setting. The patient may be monitored in the clinic for a longer duration if the institutional standards for the administration of blood products require a longer monitoring period, or if the Investigator chooses to extend the monitoring period based on their clinical judgment.

All post-infusion data points must be recorded in the electronic case report form (eCRF), including any post-dose reactions reported by or observed in the patient. Patients will receive supportive care for acute or chronic toxicity, including blood components, antibiotics, or other interventions as appropriate per local treatment guidelines. See study protocol for additional information.

If a patient experiences a reaction post-infusion, then diphenhydramine 0.25 to 0.5 mg/kg IV or orally (maximum dose 25 mg) or a different antihistamine preferred by the study site may be administered as treatment (even if received as premedication). Acetaminophen 5 to 10 mg/kg IV or orally (maximum dose 1000 mg) may also be given if it was not given as premedication or if at least 6 hours has elapsed since the prior dose. If optimal control of the infusion reaction is not

achieved, prednisone or an equivalent medication may be considered at a dose of ≤0.5 mg/kg/day prednisone equivalents. If administered, document accordingly.

17.1 Monitoring for and Management of Cytokine Release Syndrome

The following recommendations have been adapted from recommendations for patients receiving chimeric antigen receptor (CAR)-T cells who develop cytokine release syndrome (CRS).[1] Cytokine release syndrome is common following CAR-T cell therapy but remains a theoretical concern following infusion of VSTs. No cases of CRS were observed in 58 patients in the Phase 2 CHARMS study of VSTs for viral infections following allogeneic HCT.[2] Nevertheless, investigators should remain vigilant for the signs and symptoms of CRS, particularly during the first four weeks following VST infusion, and should be prepared to treat patients immediately for CRS should it develop. Investigators should also counsel patients to seek immediate medical attention if they develop concerning clinical findings. At the first sign of CRS, immediately evaluate the patient for hospitalization and institute treatment as outlined below or according to treatment protocols in use at the study site. Cytokine release syndrome typically begins within 1 to 14 days (median 2 to 3 days) after CAR-T cell therapy.[3] Suspected adverse events should be reported according to recommendations outlined in the study protocol.

It is also important to note that the common symptoms of CRS are not unique to CRS and clinicians must be cautious and exclude other causes of fever, hypotension, hemodynamic instability, and/or respiratory distress, such as an overwhelming infection.[4]

Table 4: Treatment of Cytokine Release Syndrome

CRS Grade	CRS Severity	Management
1	Prodromal syndrome: Low-grade fever, fatigue, anorexia	Observe in person; exclude infection; administer antibiotics per local guidelines if neutropenic; provide symptomatic support.
2	CRS requiring mild intervention (≥1 of the following): • High fever • Hypoxia • Mild hypotension	Administer antipyretics, oxygen, intravenous fluids and/or low-dose vasopressors as needed.
3 to 4	CRS requiring moderate to aggressive intervention (≥1 of the following): • Hemodynamic instability despite IV fluids and vasopressor support • Worsening respiratory distress, including pulmonary infiltrates increasing oxygen requirement including high-flow oxygen	Administer high-dose and/or multiple vasopressors, oxygen, mechanical ventilation and/or other supportive care as needed. Administer tocilizumab: • Patient weight <30 kg: 12 mg/kg IV over 1 hour • Patient weight ≥30 kg: 8 mg/kg IV over 1 hour (maximum dose 800 mg) If there is no clinical improvement, repeat tocilizumab after a minimum interval of 8 hours.

CRS Grade	CRS Severity	Management
	and/or need for mechanical ventilation • Rapid clinical deterioration	If there is no response to a second dose of tocilizumab, consider a third dose of tocilizumab or pursue alternative measures for treatment of CRS. Limit to a maximum total of 4 doses of tocilizumab. If there is no clinical improvement within 12 to 18 hours of the first tocilizumab dose, or if there is worsening at any time, administer methylprednisolone 2 mg/kg IV as an initial dose, then 2 mg/kg IV per day until vasopressors and high-flow oxygen are no longer needed, then taper.

Abbreviations: CRS = cytokine release syndrome; IV = intravenous.

References

1. KYMRIAH® (tisagenlecleucel) suspension for intravenous infusion, prescribing information. https://www.novartis.us/sites/www.novartis.us/files/kymriah.pdf. Accessed on 09 May 2021.
2. Tzannou I, Papadopoulou A, Naik S, et al. Off-the-shelf virus-specific T cells to treat BK virus, human herpesvirus 6, cytomegalovirus, Epstein-Barr virus, and adenovirus infections after allogeneic hematopoietic stem-cell transplantation. J Clin Oncol. 2017;35(31):3547-3557.
3. Porter DL and Maloney DG. Cytokine release syndrome (CRS). Post TW, ed. UpToDate. Waltham, MA. Updated 06 Apr 2020. https://www.uptodate.com/contents/cytokine-release-syndrome-crs. Accessed on 09 May 2021.
4. Lee DW, Santomasso BD, Locke FL, et al. ASTCT consensus grading for cytokine release syndrome and neurologic toxicity associated with immune effector cells. Biol Blood Marrow Transplant. 2019;25(4):625-638.

18 INVESTIGATIONAL PRODUCT ACCOUNTABILITY

18.1 General Accountability

The Investigator is responsible for IP accountability, reconciliation, and record maintenance during the study, including documentation of the receipt of the IP and administration to the patient. Records will be maintained indicating the receipt and dispensation of all study IP shipments. The CRA will review accountability records at regular intervals as part of the clinical site monitoring visit. The responsible cell therapy laboratory personnel or designated staff at the investigational site must keep accurate records and inventory of study IP shipments received, the IP administered per patient, the IP stored, and the IP destroyed. This information must be recorded on the Chain of Custody form (Appendix B).

The study IP **MAY NOT** be used for any purposes other than those outlined in the study protocol. Under no circumstances should the Investigator, cell therapy laboratory personnel, or other site personnel use the IP or supplies provided for any purpose other than as directed by the protocol, without prior authorization from AlloVir.

18.2 Destruction of the Investigational Product

Sites should dispose of used vials as biohazard waste in accordance with local governing regulations and clinical site SOPs/written procedures.

For unused vials, approval is required to destroy at site:

Prior to IP destruction, the SOP or written procedure for destruction be must reviewed and approved by the sponsor and/or CRO. Email approval will be filed at the site. Approval is expected if the following criteria are met:

- Site must have a documented procedure for destroying IP
- Procedure must state that destruction will follow applicable laws and regulations
- Procedure must state that the destruction will be documented, including what was destroyed, how it was destroyed, and when it was destroyed

If the site is FACT- or JACIE-accredited, approval of the IP destruction process will still need to be provided by the CRA.

Once approval of the site's IP destruction process has been received the site can proceed with the destruction of specific vials of IP as per their SOP/written procedure.

Destruction of unused IP must be documented on the Chain of Custody form (Appendix B).

IPvials (used or unused) and all infusion materials (syringes, infusion tubes, etc.) containing IP should be treated and disposed of as biohazard waste in accordance with local governing regulations and clinical site SOPs/written procedure.

19 BLINDING AND UNBLINDING PROCEDURES

19.1 Maintaining the Blind

The integrity of the study blind and randomization procedures must be maintained over the course of the study. Shipment of vials containing IP will be triggered by the IRT following the randomization of a patient. Upon arrival of IP at the site, the site staff will follow the procedures laid out in this Cell Therapy Manual and in alignment with their site's SOPs.

Upon randomization of a patient, the IRT assigns specific vials within the to be administered for the first dose which are documented on the IRT Transaction Report.

The IRT will assign specific vial(s) for the subsequent dose(s) as applicable per the Protocol.

19.2 Blinded Site Staff Responsibilities

The investigators, research staff, and patients are to remain blinded to treatment assignment.

19.3 Unblinded Site Staff Responsibilities

Unblinded cell therapy lab staff must ensure the appropriate procedures are in place to keep blinded individuals (ie, investigators, research staff, and patients) blinded to treatment assignment.

19.4 Emergency Unblinding Procedure

The blind is anticipated to be broken only in extreme situations. Before any potential unblinding, the reasons and rationale for the unblinding should be discussed with AlloVir, and the medical lead or designee. The Investigator and designated study site staff are the only personnel at the study site who are authorized to decide to unblind a patient's treatment assignment group in an emergency situation.

In the case of an emergency, the Investigator (and/or a delegated sub-investigator if the Investigator is unavailable) has the sole responsibility for determining if unblinding of a participant's study treatment assignment is warranted. Participant safety must always be the first consideration in making such as determination. If the Investigator decides that unblinding is warranted, the Investigator should make every effort to contact the medical lead prior to unblinding a participant's IP assignment unless this could delay emergency treatment of the participant. Please consult IRT Site User Reference Guide for instructions.

If a participant's treatment assignment is unblinded, the Sponsor or medical lead must be notified within 24 hours of breaking the blind. The date and reason that the blind was broken must be recorded in the source documentation and electronic CRF, as applicable.

Unblinding at the clinical site for any reasons other than a medical emergency will be considered a protocol deviation.

20 LIST OF APPENDICES

Appendix A: Cryoport Temperature Stability Report

Appendix B: Chain of Custody Form

Appendix C: Syringe Label

Appendix D: Azenta BioInventory Package Manifest

Appendix E: IRT Shipment Request Form

Appendix F: Issue Reporting Form

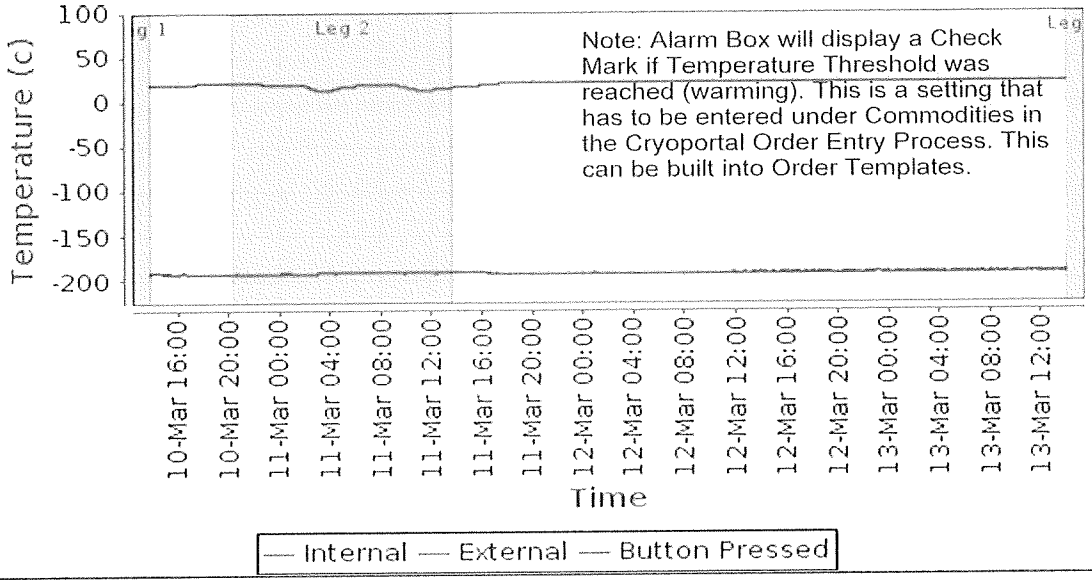
Appendix G: Dose Worksheet

Appendix H: AT-Adapt User Guide

APPENDIX A. CYROPORT TEMPERATURE STABILITY REPORT

Temperature Stability Report - Order #
Package #1 Logger #
Lot/Serial Number:

ALARM



Alarm Zones	Allowed Time	Total Time	No. of violations	Status
No band defined		Internal Temperature Stats Summary is displayed under Logging Results		

Logging Results

Internal High/Low/Average/Std Dev:	-191.9/-194.6/-192.6/0.3 °C	Transit Start at:	03/09/2020
External High/Low/Average/Std Dev:	21.2/11.3/19.5/2.1 °C	Arrived at:	03/16/2020
		Alarm at:	
		File created:	03/16/2020

Condition Monitoring System

Part Number:	ACC-9123	Description:	SmartPak II Data Logger (PT300D)
Serial Number:		Battery Voltage:	4.13 V - 3.88 V
Calibration Certificate #:	Not Required	Calibration Due Date:	Not Required
Part Number:		Description:	Thermocouple SmartPak II
Serial Number:			
Calibration Certificate #:		Calibration Due Date:	10/07/2020
Recorded By:		Date:	03/09/2020

CONFIDENTIAL
FOR INFORMATIONAL USE ONLY

APPENDIX C. SYRINGE LABEL

ALVR105 or Placebo
Dispersion for Intravenous Infusion
AlloVir, Inc.
P-105-201
Subject ID: _ _ _ - _ _ _ _
Vial Number: _ _ _
Vial Number: _ _ _

For Investigational Use Only
For additional information, please refer to Cell Therapy Manual

APPENDIX D. Azenta (formerly Brooks) BIOINVENTORY PACKAGE MANIFEST

Example - For Reference Only

Brooks Life Sciences
2910 Fortune Circle West
Suite E
Indianapolis, IN 46241
Tel: 317-390-1866

Ship To: Site Name
Site Address

Contact:
Number:

Shipment No: XXXXXXXX
Req. Delivery Date: DD-MON-YYYY
Carrier: World Courier

Project: P-105-202
Storage Temp(s): -190° C

Group(s):
Sample Type(s):

Pkg Pos	Originating ID	ISISS Registration

Package XXXXXX (# samples in package)

APPENDIX E. IRT SHIPMENT REQUEST FORM

Allovir
P-105-201
Unblinded Shipment Request

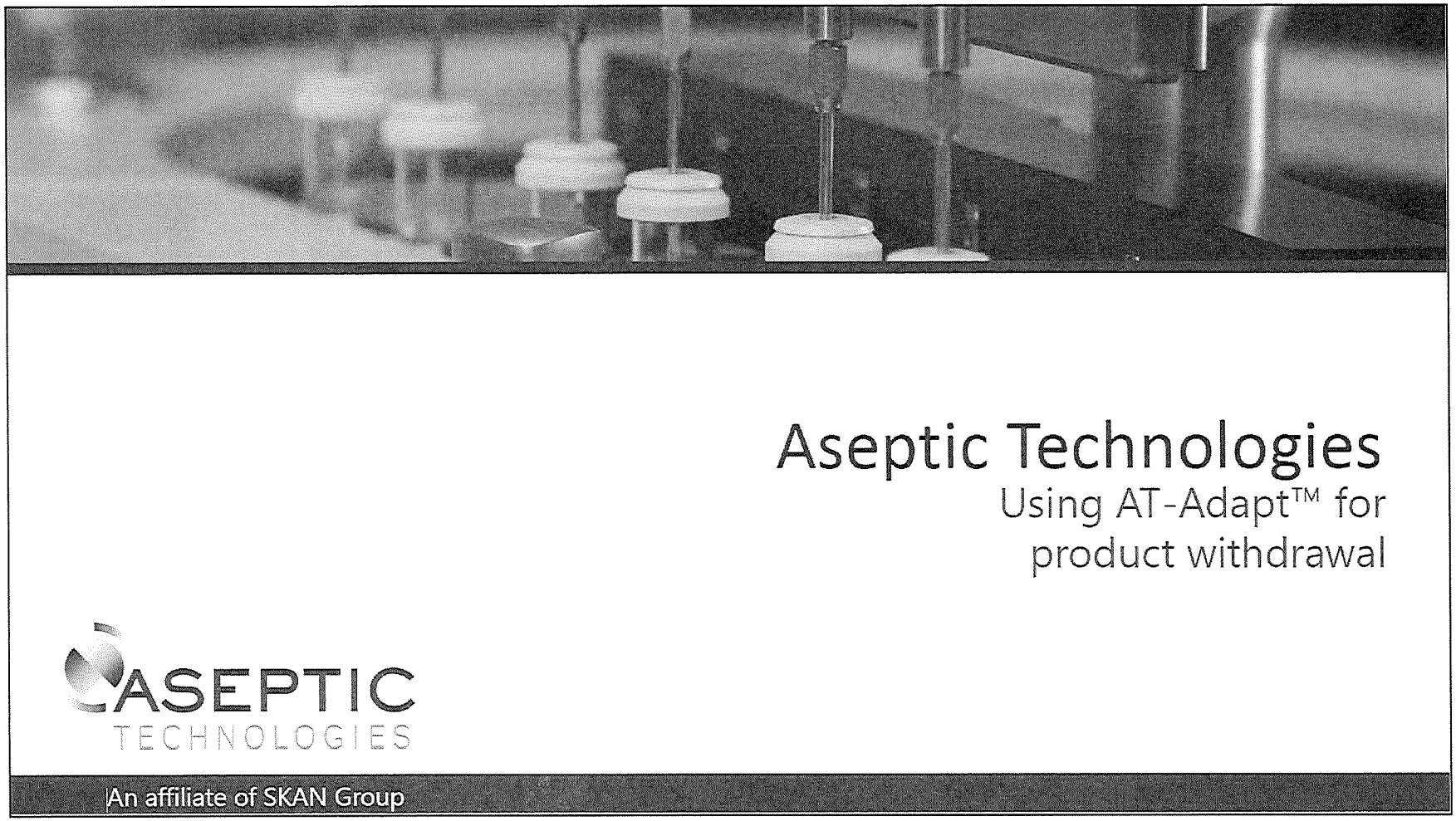
Shipment ID	S-3-89-1308	Shipment Type	MANUAL
Date Requested	01-Jun-2021	Fill Type	FULL
Supplying Warehouse	Azenta US, Inc.	Site Phone Number	123-123-1234
Destination Site Number	123	Site Shipping Address	ICON 1234 Dairy Ashford Sugar Land, TX, 77479 United States

Site Investigator	Nausheen Siddiqui
Drug Contact Name	MS. Nausheen ..... Siddiqui
Drug Contact Email	test@test.com
Patient Number	123-1122

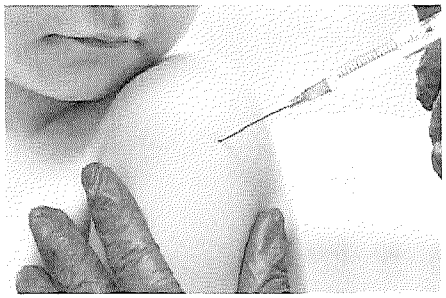
Please ship the following:

Lot Number + Vial No	Expiration Date
128-ZZ-23TSTB-113	31-Jan-2025
128-ZZ-23TSTB-114	31-Jan-2025
128-ZZ-23TSTB-115	31-Jan-2025
128-ZZ-23TSTB-116	31-Jan-2025
128-ZZ-23TSTB-117	31-Jan-2025
128-ZZ-23TSTB-118	31-Jan-2025
128-ZZ-23TSTB-119	31-Jan-2025
128-ZZ-23TSTB-120	31-Jan-2025
128-ZZ-23TSTB-121	31-Jan-2025
128-ZZ-23TSTB-122	31-Jan-2025

APPENDIX H. AT-ADAPT USER GUIDE

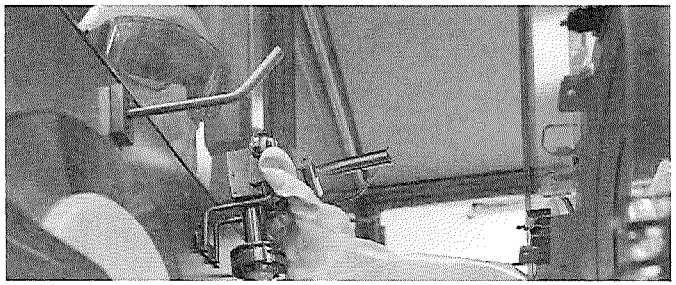


Values



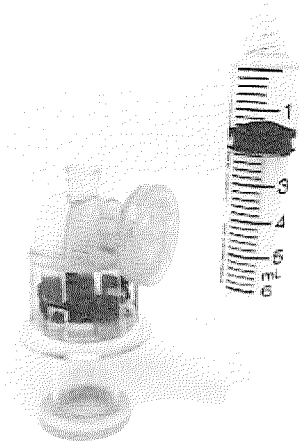
The constant improvement of cGMP guidelines, in order to avoid any possible contamination of the aseptic process, does not necessarily imply an escalation in the complexity of the equipment for aseptic production and packaging.

We develop, manufacture and market equipment and devices that guarantee optimal sterility assurance level and complies with latest regulatory requirements, while simplifying the validation and operation processes.



AT-Adapt™

Overview



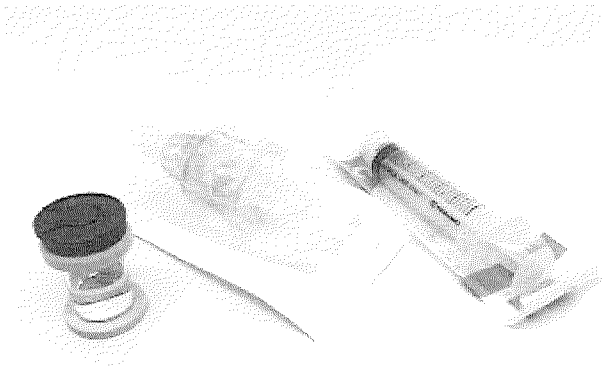
The AT-Adapt™ is a stand-alone, single-use, disposable device which permits access to an AT-Closed Vial® (2, 6, 10, 20 and 50mL format) without the use of a needle.

The device is intended for use by healthcare professionals in a wide variety of healthcare environments, including hospitals, healthcare facilities and pharmacies.

Together always one step ahead www.aseptictech.com 3

AT-Adapt™

Material

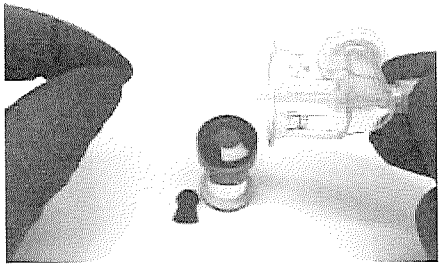


A processed (filled and capped) AT-Closed Vial®;
An AT-Adapt™;
A syringe with luer connection.

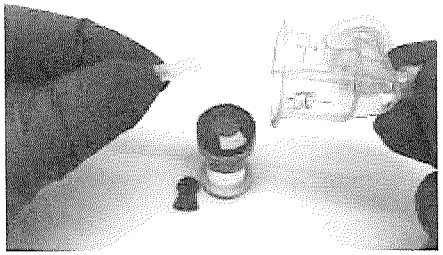
AT-Adapt™

Process

The individual packaging of the AT-Adapt™ is peeled



The flip-off cap protecting the AT-Closed Vial® stopper is removed



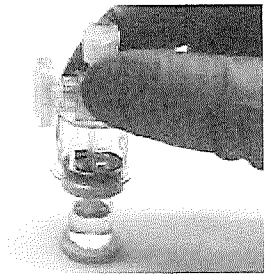
The protection of the spike of the AT-Adapt™ is removed

Together always one step ahead www.aseptictech.com 5

AT-Adapt™

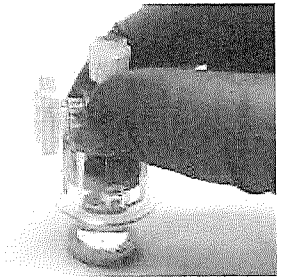
Process

Attaching the AT-Adapt™ to the AT-Closed Vial® is a 3 step process:

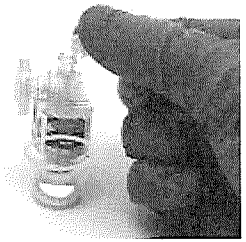


Step 1: **ATTACH** the AT-Adapt™ to the AT-Closed Vial®.

Do not press too firmly to avoid tabs of the AT-Adapt™ to be locked on the top ring of the AT-Closed Vial®.



Step 2: **SPIKE** the AT-Closed Vial® by moving the AT-Adapt™ in a downward motion into the vial. Spike should be perpendicular to stopper. Do not insert at an angle.



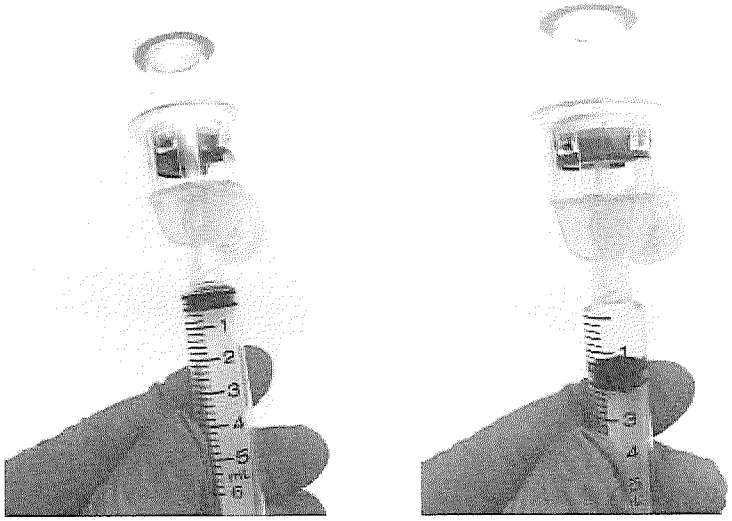
Step 3: Holding the AT-Closed Vial®, **the AT-Adapt™ shall be lifted up until the lower tab touches the cap (see yellow circle). This ensures an optimal needle positioning for maximal product withdrawal.**

The cap protecting the luer connection can be removed.

Together always one step ahead www.aseptictech.com 6

AT-Adapt™

Process



A syringe is connected and the product is withdrawn from the AT-Closed Vial® , upside down.

Do not put pressure (air) in the vial with the syringe (prior retrieving)

Together always one step ahead www.aseptictech.com 7

Copyright by Aseptic Technologies S.A.

Signature Page for P-105-201 Cell Therapy Manual v4.0 09 May 2022
VV-CLIN-000066 v4.0

Approval Task	Ken Kamineni Clinical 09-May-2022 14:15:45 GMT+0000

Approval Task	William Marshall Clinical 09-May-2022 14:20:03 GMT+0000

Approval Task	Tim Hanson Manufacturing 09-May-2022 15:00:40 GMT+0000

Signature Page for P-105-201 Cell Therapy Manual v4.0 09 May 2022
VV-CLIN-000066 v4.0

APEENDIX B. ALLOVIR CHAIN OF CUSTODY FORM V4.0

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

SHIPMENT INFORMATION: DOSES 1 THROUGH 5 (10 VIALS)			
Order ID: *Listed on IRT Shipment Request Form*	_ _ _ _ _ _		
Check Documentation Received:	☐ Azenta BioInventory Package Manifest ☐ IRT Shipment Request ☐ Certificate(s) of Conformance ☐ Shipper return labels ☐ Safety Data Sheet (SDS) ☐ Secondary labels (1 per vial)	Was there intact zip ties present on the cryoshipper upon delivery?	☐ Y ☐ N
		Were all contents listed on the IRT Shipment Request received?	☐ Y ☐ N
Date and Time Vials removed from shipper:	___ / _____ / _____ _____ DD MMM YYYY HH:MM	Did the cryoshipper Temperature Stability Report note any temperature alarms occurring during transit?	☐ Y ☐ N
If the contents were missing from the shipment or if a temperature alarm occurred during shipment, please follow the issue reporting instructions in the Cell Therapy Manual.			

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

SHIPMENT INFORMATION: DOSES 6 THROUGH 8 (6 VIALS)			
Order ID: *Listed on IRT Shipment Request*	_ _ _ _ _ _		
Check Documentation Received:	☐ Azenta BioInventory Manifest Package ☐ IRT Shipment Request ☐ Certificate(s) of Conformance ☐ Shipper return labels ☐ Safety Data Sheet (SDS) ☐ Secondary labels (1 per vial)	Was there an intact zip tie present on the cryoshipper upon delivery?	☐ Y ☐ N
		Were all contents listed on the IRT Shipment Request received?	☐ Y ☐ N
Date and Time Vials removed from shipper:	___ / _____ / _____ _____ DD MMM YYYY HH:MM	Did the cryoshipper Temperature Stability Report note any temperature alarms occurring during transit?	☐ Y ☐ N
If the contents were missing from the shipment or if a temperature alarm occurred during shipment, please follow the issue reporting instructions in the Cell Therapy Manual.			

It is the responsibility of the site to ensure that the Investigational Product is stored in vapor phase liquid nitrogen (LN2) at ≤ -150°C upon receipt and removal from the shipper.

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

	RECEIPT			ADMINISTRATION			DESTRUCTION		
Vials *(Lot Number; Vial Number)*	**Received in Good Condition** *(Mark N/A for vials not received)*	**Date Received** *(dd-MON-yyyy)*	**Received and Unpacked By** *(Initials)*	**Administered to Patient**	**Date Administered** *(dd-MON-yyyy)*	**Dispensed By** *(Initials)*	**Date and Time of Destruction** *(dd-MON-yyyy, HH:MM)*	**Destroyed By** *(Initials)*	**CRA Initials/Date** *(dd-MON-yyyy)*
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

	RECEIPT			ADMINISTRATION			DESTRUCTION		
Vials *(Lot Number; Vial Number)*	**Received in Good Condition** *(Mark N/A for vials not received)*	**Date Received** *(dd-MON-yyyy)*	**Received and Unpacked By** *(Initials)*	**Administered to Patient**	**Date Administered** *(dd-MON-yyyy)*	**Dispensed By** *(Initials)*	**Date and Time of Destruction** *(dd-MON-yyyy, HH:MM)*	**Destroyed By** *(Initials)*	**CRA Initials/Date** *(dd-MON-yyyy)*
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					
126 - __ - ______; ___	☐ Yes ☐ No ☐ N/A			☐ Y ☐ N					

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

DAY 1 INFUSION (SECONDARY LABEL)

Attach secondary label below (ONE FOR EACH VIAL THAT YOU PREPARE FOR INFUSION)

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

WEEK 1 INFUSION (SECONDARY LABEL)
Attach secondary label below (ONE FOR EACH VIAL THAT YOU PREPARE FOR INFUSION)

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

WEEK 2 INFUSION (SECONDARY LABEL)
Attach secondary label below (ONE FOR EACH VIAL THAT YOU PREPARE FOR INFUSION)

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

WEEK 4 INFUSION (SECONDARY LABEL)

Attach secondary label below (ONE FOR EACH VIAL THAT YOU PREPARE FOR INFUSION)

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

WEEK 6 INFUSION (SECONDARY LABEL) **IF APPLICABLE**

Attach secondary label below (ONE FOR EACH VIAL THAT YOU PREPARE FOR INFUSION)

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

WEEK 8 INFUSION (SECONDARY LABEL) **IF APPLICABLE**
Attach secondary label below (ONE FOR EACH VIAL THAT YOU PREPARE FOR INFUSION)

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

WEEK 10 INFUSION (SECONDARY LABEL) **IF APPLICABLE**
Attach secondary label below (ONE FOR EACH VIAL THAT YOU PREPARE FOR INFUSION)

CHAIN OF CUSTODY FORM V4.0 (UNBLINDED DOCUMENT)

PATIENT AND INFORMATION			
Site Number:		Investigator Name:	
Patient ID: (Ex: Site # - Patient #)			

WEEK 12 INFUSION (SECONDARY LABEL) **IF APPLICABLE**
Attach secondary label below (ONE FOR EACH VIAL THAT YOU PREPARE FOR INFUSION)

APPENDIX F. IP ISSUE REPORTING FORM

ALLOVIR P-105-201
09MAY2022 V 4.0

Site Instructions: In the event of an issue regarding investigational product (IP) for Protocol P-105-201 please follow the reporting instructions in the Cell Therapy Manual and email this form with sections A and B, C, or D completed to your unblinded CRA.

Once a decision has been made, ICON will communicate the decision to the site via email and include the completed form. **Please file the completed form.**

SECTION A: SITE AND ISSUE INFORMATION

Site Name / Number		Institution	
PI Name		Address	
Reported by *Print name and title*		Signature/Date	
Email		Telephone	
Please check appropriate box:	☐ IP temperature excursion *(please complete section B)* ☐ Receipt of IP at site *(please complete section C)* ☐ IP product complaint *(please complete section D)* ☐ Other *(please complete section D)*		
Was this an urgent issue?	☐ Yes *(If yes, please complete the box below)* ☐ No		
Please describe the actions taken at the time the urgent issue was discovered.			

SECTION B: TEMPERATURE EXCURSION INFORMATION

Product Name *Storage Condition is vapor phase liquid nitrogen (LN2) at ≤ -150°C*	ALVR105 or placebo	Affected Lot + Vial #s:	126 - _ _ - _ _ _ _ _ ; _ _ _ 126 - _ _ - _ _ _ _ _ ; _ _ _ 126 - _ _ - _ _ _ _ _ ; _ _ _ 126 - _ _ - _ _ _ _ _ ; _ _ _
Did the excursion occur during shipment of IP to the site?	☐ Yes *If yes, please attached the Cryoport temperature stability report and submit the signed form. Do not complete the remainder of section B.* ☐ No		
Start Date of Excursion (dd-MMM-yyyy)		Duration of Excursion (HH:MM)	
Start Time of Excursion (24H HH:MM)			

SECTION B: TEMPERATURE EXCURSION INFORMATION			
Date of Discovery (dd-MMM-yyyy)		Maximum temperature reached during excursion	
Description and Cause of Excursion			

SECTION C: RECEIPT OF IP AT SITE			
Shipment Order ID:		Affected Lot + Vial #s:	126 - _ _ - _ _ _ _ _ ; _ _ _ 126 - _ _ - _ _ _ _ _ ; _ _ _ ☐ N/A 126 - _ _ - _ _ _ _ _ ; _ _ _ ☐ N/A 126 - _ _ - _ _ _ _ _ ; _ _ _ ☐ N/A
Please describe the issue(s) identified:			

SECTION D: PRODUCT COMPLAINT OR OTHER ISSUE INFORMATION	
Affected Lot + Vial #s:	126 - _ _ - _ _ _ _ _ ; _ _ _ 126 - _ _ - _ _ _ _ _ ; _ _ _ ☐ N/A 126 - _ _ - _ _ _ _ _ ; _ _ _ ☐ N/A 126 - _ _ - _ _ _ _ _ ; _ _ _ ☐ N/A
Please describe the issue(s) identified:	

Please send a completed form to your Unblinded CRA and wait for further instructions.

SECTION E: ALLOVIR/ICON USE ONLY			
Assessment	☐ Acceptable for use ☐ NOT acceptable for use. Site to destroy affected vials. ☐ Other - see notes.		
Notes			
Name (Print)	Title	Signature	Date

APPENDIX G. DOSE WORKSHEET

ALLOVIR P-105-201
09MAY2022 V 4.0

DOSE WORKSHEET
Site Instructions: Complete this worksheet for **each dose** of Investigational Product prepared and administered to the patient. Some parts maybe completed only by unblinded or blinded site staff. Part A: Patient and Vial Information Part B: Investigational product THAW and PREPARATION OF ADMINISTRATION SYRINGE Part C: Administration of investigational product Part D: Flush **If an issue arises, please follow the issue reporting instructions in the Cell Therapy Manual.**

PART A: PATIENT AND VIAL INFORMATION – COMPLETED BY CELL THERAPY STAFF/PHARMACIST			
Site Number:		Investigator Name:	
Patient ID #:			
Visit #:	☐ Day 1 (Dose 1) ☐ Week 1 (Dose 2) ☐ Week 2 (Dose 3) ☐ Week 4 (Dose 4) ☐ Week 6 (Dose 5) ☐ Week 8 (Dose 6) ☐ Week 10 (Dose 7) ☐ Week 12 (Dose 8)		
Date of randomization:	___ / _____ / _____ DD MMM YYYY		
IRT assigned Vial 1: Vial #	___	Vial 1 Expiration Date	___ / _____ / _____ DD MMM YYYY
IRT assigned Vial 2: Vial #	___	Vial 2 Expiration Date	___ / _____ / _____ DD MMM YYYY
Completed By:	Print Name:	Signature:	___ / _____ / _____ DD MMM YYYY
Verified By:	Print Name:	Signature:	___ / _____ / _____ DD MMM YYYY

PATIENT ID #:	
Visit #:	☐ Day 1 (Dose 1) ☐ Week 1 (Dose 2) ☐ Week 2 (Dose 3) ☐ Week 4 (Dose 4) ☐ Week 6 (Dose 5) ☐ Week 8 (Dose 6) ☐ Week 10 (Dose 7) ☐ Week 12 (Dose 8)

PART B: INVESTIGATIONAL PRODUCT THAW AND PREPARATION OF ADMINISTRATION SYRINGE

This section is to be completed by cell therapy/pharmacy or responsible party for thawing and preparing the syringe, After completing this section, please hand off the dosing worksheet to the infusion staff.
Administration of Investigational Product is to be completed within 30 minutes of thaw completion.
If thawing multiple cryovials, thaw all vials at the same time in the same manner.

Date and Time of Removal of Vials from LN Storage	___ / _____ / _____ _____ DD MMM YYYY HH:MM	Was the vial / Were the vials intact, sealed, and frozen?	☐ Yes ☐ No
Date and Time of Thaw Completion	___ / _____ / _____ _____ DD MMM YYYY HH:MM	Indicate method of thawing and thawing temperature:	☐ Water bath ☐ Dry-Block Temperature: _____ °C
Prior to thaw, were the lot and vial numbers listed on the vials double verified against the IRT assignment?	☐ YES ☐ NO	When IP was drawn into the syringe, were the vial numbers listed on the vials double verified against the vial numbers listed on the syringe label?	☐ YES ☐ NO

Was the patient ID listed on the syringe label double verified against the IRT assignment? ☐ YES ☐ NO	Was a **<u>total</u>** of 4mL of IP drawn into the 5mL Luer Lock Syringes(s)? (Preparation at bedside requires 2 dosing syringes, with 2mL of IP in each) ☐ YES ☐ NO *IF NO, please complete the issue reporting form, as applicable.

Completed By:	Print Name:	Signature:	___ / _____ / _____ DD MMM YYYY
Verified By:	Print Name:	Signature:	___ / _____ / _____ DD MMM YYYY

PATIENT ID #:	
Visit #:	☐ Day 1 (Dose 1) ☐ Week 1 (Dose 2) ☐ Week 2 (Dose 3) ☐ Week 4 (Dose 4) ☐ Week 6 (Dose 5) ☐ Week 8 (Dose 6) ☐ Week 10 (Dose 7) ☐ Week 12 (Dose 8)

PART C: ADMINISTRATION OF INVESTIGATIONAL PRODUCT – COMPLETED BY INFUSION STAFF

Follow IP administration instructions in Cell Therapy Manual Section 13 - Administration

Date and Time of Administration Start	___ / _____ / _____ _____ DD MMM YYYY HH:MM	Date and Time of Administration Completion *(not including post-infusion flush)*	___ / _____ / _____ _____ DD MMM YYYY HH:MM
Was administration completed within 30 minutes of thaw completion? ☐ YES ☐ NO		Was 4mL of IP administered to the study patient? ☐ YES ☐ NO *IF "NO" was marked, please complete volume administration below and complete issue reporting form, as applicable.	
Confirm that the Hemo-Nate syringe filter was utilized:		☐ YES	
Completed By:	Print Name:	Signature:	___ / _____ / _____ DD MMM YYYY
Verified By:	Print Name:	Signature:	___ / _____ / _____ DD MMM YYYY
The following fields are to be completed only if the dose was interrupted or the entire volume was not administered.			
If the dose was interrupted, reason for dose interruption:			
Date and Time of Administration Pause	___ / _____ / _____ _____ DD MMM YYYY HH:MM	Date and Time of Administration Re-start	___ / _____ / _____ _____ DD MMM YYYY HH:MM
Total volume administered	_____ mL	Estimated remaining volume after administration completion: ***(Complete only if the entire volume was not given)***	_____ mL

PART D: FLUSH

Follow IP administration instructions in Cell Therapy Manual Section 13 - Administration

Date and Time of Flush Start	___ / _____ / _____ _____ DD MMM YYYY HH:MM	Date and Time of Flush Completion	___ / _____ / _____ _____ DD MMM YYYY HH:MM
Saline Flush Volume	_____ mL		
Completed By:	Print Name:	Signature:	___ / _____ / _____ DD MMM YYYY
Verified By:	Print Name:	Signature:	___ / _____ / _____ DD MMM YYYY

IP vials and all infusion materials (syringes, infusion tubes, etc.) containing IP should be treated and disposed of as biohazard waste in accordance with local governing regulations and clinical site SOPs.