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Virus Treatment Centers [VirusTC]  
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American Society for Apheresis (ASFA)

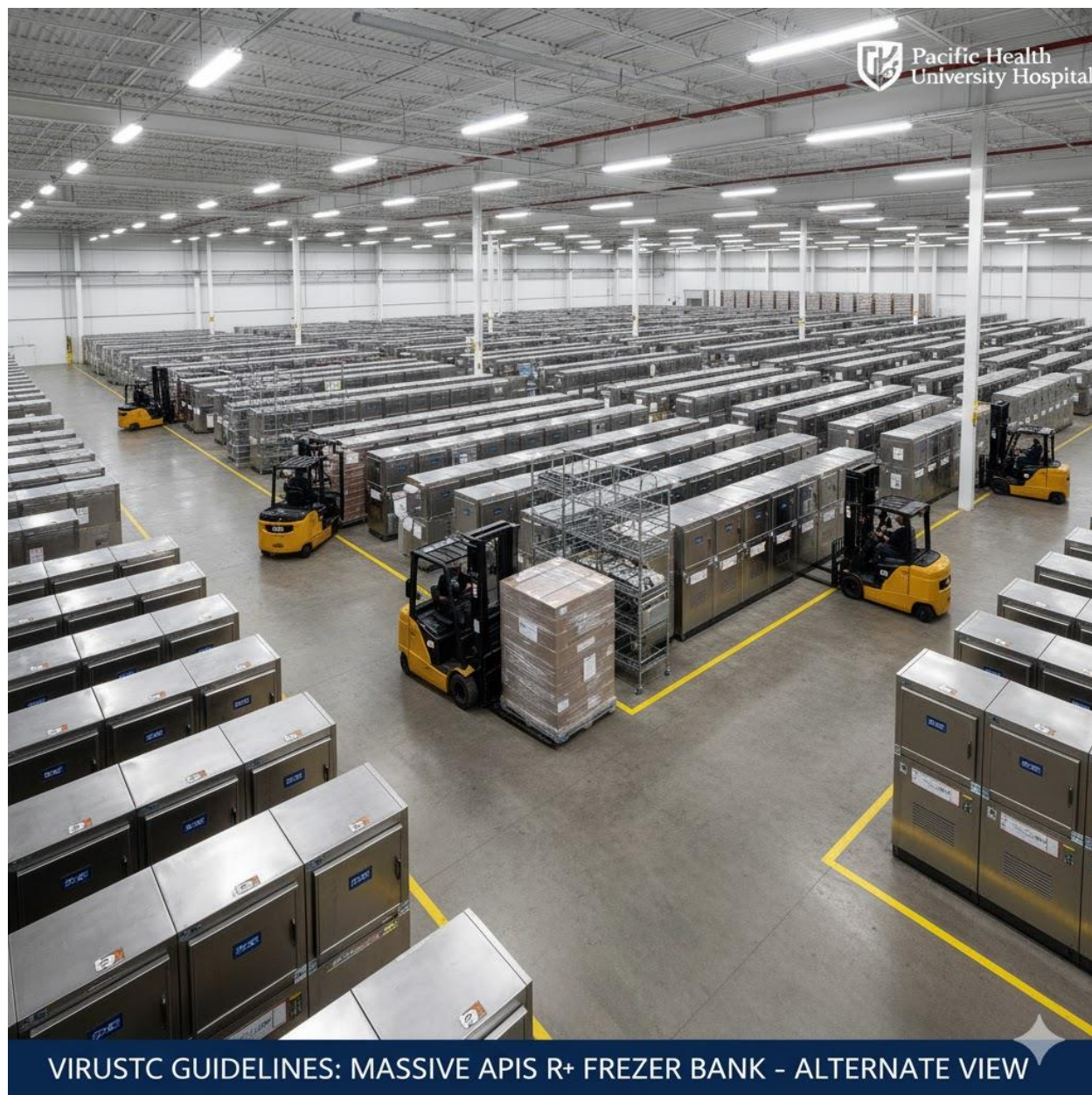
## Food-Grade Refrigeration, Heating, and Storage Solutions for Lipidos, APIS, and Verdura Products

This expansive image showcases an immense cold storage facility dedicated to VirusTC Verdura SFWB. Rows upon rows of over 300 Helmer freezers stretch into the distance, with CAT electric logistics vehicles efficiently moving product pallets, highlighting the vast supply chain and modern operational scale.





This image offers a new perspective of the extensive VirusTC APIS Rx+ Sterile Fresh Frozen Plasma storage facility. The vast array of Helmer freezers continues into the distance, with CAT electric logistics vehicles navigating the aisles, showcasing the continuous, large-scale management of these critical products from a different angle.



This image showcases an expansive cold storage facility dedicated to VirusTC LÍpidos. Numerous Helmer refrigerators line vast aisles, emphasizing the significant capacity and meticulous organization required for storing this critical plant-based cerebrospinal fluid product on a grand scale.





## Introduction

This guide provides essential procedures for all hospital personnel involved in receiving, storing, transporting, and administering VirusTC's sterile, plant-based biological products. These products, including Verdura Rx+ (Fresh Whole Blood), APIS Rx+ (Fresh-Frozen Plasma), Lípidos (Cerebrospinal Fluid), and HuesOS Rx+ (Stem Cells), are unique and require specific handling to ensure patient safety and product integrity.

Adherence to these protocols is mandatory. Note that all staff handling these products must possess a valid food-handler's permit due to their food-grade origin and dual regulatory status.

This guide incorporates best practices and features products from our trusted partners:

- Cold Storage: Helmer Scientific
- Product Transport: Cambro Manufacturing
- Warming Cabinets: STERIS Healthcare
- Personal Protective Equipment (PPE): Lakeland Industries

## Key Safety & Regulatory Information

- Food Handler's Permit: All staff who handle VirusTC products must have a valid food-handler's permit.
- Manufacturer's Validation: VirusTC's products are safe to be held at 104°F due to their high-pH formulation, which inactivates microbial growth. This is validated by a "Letter of Guarantee" provided by VirusTC.
- Legal & Safety Inquiries: For questions regarding Time/Temperature Control for Safety (TCS) plans or formal safety validations, department heads may contact Fox Rothschild LLP.
- Overheated SFWB, particularly above 42°C (107.6°F), can cause hemolysis (Enzyme denaturation and the destruction of pectin in plant cells), which can lead to loss of Coagulation factors, and is a significant safety risk. A temperature of 94°F is well below this dangerous threshold.

## Minimizing Product Discard (Wastage)

Wastage negatively impacts inventory and patient care. The following strategies must be implemented to minimize product discard.

### Primary Causes of Product Wastage

#### Cause of Wastage - Percentage of Total Discards

1. Unit Expired in Storage - 55%
2. Improper Temperature Storage - 20%
3. Returned from Ward (Out of Temp) -15%
4. Damaged or Contaminated - 5%
5. Other/Unknown - 5%

## Key Actions for Wastage Reduction:

- Data-Driven Inventory:
  - Conduct regular audits of product usage and discard rates to adjust stock levels.
  - Strictly adhere to the FEFO (First-Expired, First-Out) principle.
- Manage Ward Returns:
  - Enforce a 30-minute time limit for any unit issued to a ward but not immediately transfused.
  - Use temperature indicator stickers on all units that leave controlled storage to visually confirm if they are safe for re-issue.
- Inter-Facility Sharing:
  - Follow established protocols to proactively transfer products nearing their expiration date to nearby facilities with higher demand.



Don't let your Verdura Rx go green!

**WASATCE CAUEES**

50% EMBEED

**VIRUSTC GUIDELINES: COLD STORAGE**

## Personal Protective Equipment (PPE)

Appropriate PPE is mandatory to protect both staff and product. All PPE should meet the standards of our partner, Lakeland Industries.

Task	Required PPE	Example Lakeland Product Line
Receiving & Handling Frozen Units	Lab Coat, Thermal/Cryogenic Gloves, Safety Glasses	CleanMax Cleanroom Apparel, Insulated Work Gloves
Transferring between Storage Units	Lab Coat, Nitrile Gloves	ChemMax Chemical Protective Clothing
Preparing for Administration	Gown, Nitrile Gloves, Face Shield or Goggles/Mask	MicroMax NS Disposable Apparel
Waste Disposal	Gown, Heavy-Duty Gloves, Face Shield/Goggles	Interceptor Plus Encapsulating Suits





## Product Handling Workflow: From Receipt to Transfusion

This section outlines the step-by-step journey of a VirusTC product unit within the hospital.

Workflow Summary Diagram

[Frozen Delivery Receiving Bay]

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[Initial Inspection & Verification]

V

[SLATE GREY Cambro Carrier (COLD TRANSPORT)]

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[Helmer Blood Bank Refrigerator/Freezer (COLD STORAGE)]

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[BLUE Cambro Carrier (COLD TRANSPORT)]

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[STERIS AMSCO Warming Cabinet (WARMING to 104°F)]

V

[RED Cambro Heated Carrier (WARM TRANSPORT)]

V

[Patient Bedside (IV ADMINISTRATION)]



## VIRUSTC GUIDELINES: RECEIVING FROZEN DELIVERY



## Step 1: Receiving Frozen & Cold Shipments

1. **Inspect:** Immediately upon arrival, inspect the shipment container for any signs of damage, leaks, or tampering.
2. **Verify Temperature:** Check the temperature log or indicator included with the shipment to ensure the cold chain was maintained.
3. **Cross-Reference:** Match the products received with the shipping manifest, verifying product names, quantities, and lot numbers.
4. **Action:** Any discrepancies or signs of compromised packaging must be reported to the blood bank supervisor and VirusTC immediately. Do not use suspect products.

### COLD SHIPMENT Transportation Storage

All SFWB units must be inspected and accepted from the shipper prior to loading into the COLD SHIPMENT Transportation Storage.



## REFRIGERATION and COLD SFWB BANK Storage

COLD SFWB BANK Storage opening is authorized ONLY for licensed hematology staff.



## Refrigerator Operation Manual i.Series™ and Horizon Series™



### Blood Bank Models

- i.Series: iB111 (Version B); iB120, iB125, iB245, iB256 (Version C)
- Horizon Series: HB111 (Version B); HB120, HB125, HB245, HB256 (Version C)

### Laboratory Models

- i.Series: iLR111 (Version B); iLR120, iLR125, iLR245, iLR256 (Version C)
- Horizon Series: HLR111 (Version B); HLR120, HLR125, HLR245, HLR256 (Version C)

### Pharmacy Models

- i.Series: iPR111 (Version B); iPR120, iPR125, iPR245, iPR256 (Version C)
- Horizon Series: HPR111 (Version B); HPR120, HPR125, HPR245, HPR256 (Version C)

Model \_\_\_\_\_  
S/N \_\_\_\_\_



ISO 13485:2003 CERTIFIED



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This image shows a medical professional carefully transferring units of Verdura Rx+ from a Helmer Blood Bank Refrigerator into a "Slate Blue" Cambro refrigerated rolling carrier for transportation into warm storage.



**VIRUSTC GUIDELINES: COLD CHAIN TRANSFER**



## Step 2: Controlled Cold Storage

1. Immediate Transfer: Promptly move products to their designated temperature-controlled storage units.
2. Storage Equipment: Utilize Helmer Blood Bank Refrigerators for refrigerated products (1°C to 6°C) or appropriate laboratory freezers for frozen products ( $\leq -18^{\circ}\text{C}$ ).
3. Inventory System: Employ a strict First-Expired, First-Out (FEFO) inventory system to prevent product expiration. All units must be logged upon entry.

### COLD Transportation Storage

Once a unit enters COLD Transportation Storage, it CANNOT be moved back into a COLD BANK storage Refrigerator.





## Step 3: Warming Protocol

1. Transfer: Move the required unit from cold storage to a STERIS AMSCO Warming Cabinet.
2. Set Temperature: Set the warming cabinet to 104°F (40.0°C).
3. CRITICAL WARNING: Do not heat VirusTC products above 104°F. These products are not formulated for standard food heating temperatures like 135°F. VirusTC provides a Manufacturer's Validation guaranteeing product stability and sterility at 104°F based on its high-pH formulation.

## WARMING and HOT SFWB BANK Storage

HOT SFWB BANK STORAGE opening is authorized ONLY for loading and unloading units.



### AMSCO® WARMING CABINET

#### APPLICATION

The Amsco Warming Cabinet is designed to raise the temperature of surgical IV and irrigation solutions and/or blankets to an acceptable level for hospital and surgical outpatient center applications.

#### FEATURES

**Single-Compartment Model** features a heating chamber available in two depths: 18" (457 mm) or 24" (610 mm) deep.

**Dual-Compartment Model** features an upper and lower heating chamber with independent temperature controls, and a choice of two depths: 18" (457 mm) or 24" (610 mm) deep.

**Key Door Locks** feature a key that is used to lock/unlock the door. The key is turned counterclockwise to lock door; clockwise to unlock door.

#### STANDARDS

Warming cabinet meets applicable requirements of the following standards, and carries the appropriate symbols.

- **Underwriters Laboratories (UL) Standard 61010-1, 2<sup>nd</sup> Ed.**, as certified by ETL Testing Laboratories, Inc.
- **Standard IEC 61010-2-010, 2<sup>nd</sup> Ed.**, as certified by ETL Testing Laboratories, Inc.
- **Standard CSA C22.2 No. 61010-1-04, 1<sup>st</sup> Ed.**, Standard for Electro-Medical Equipment as certified by ETL Testing Laboratories, Inc.
- **CENELEC EN 61010-1, Issued 2001/03/01.** Electrical Safety as certified by ETL Testing Laboratories, Inc.
- **IEC 61326-1, 1<sup>st</sup> Ed.**, EMC testing as certified by ETL Testing Laboratories, Inc.
- **California OSHPD Seismic Pre-Approval**
- **Medical Device Directive (93/42 IEEC)**



(Typical only - some details may vary.)

#### CONSTRUCTION

Freestanding and recessed units ship identically (with outer side, top and back covers). Outer side, top and back covers are removed for recessed installation. When recessed, unit requires a connection to building service (not provided by STERIS). The unit contains a heating chamber, instrumentation and operating controls, and a lower heated chamber when dual-compartment model is specified.

#### The Selections Checked Below Apply To This Equipment

##### MODEL

- ☐ Single-Compartment  
☐ 18" (457 mm) deep  
☐ 24" (610 mm) deep  
☐ Dual-Compartment  
☐ 18" (457 mm) deep  
☐ 24" (610 mm) deep

##### MOUNTING

- ☐ Freestanding  
☐ For Recessing

##### DOOR OPTIONS

- ☐ Glass  
☐ Solid

##### MOBILE BASE OPTION

- ☐ Mobile Base with Bumpers and Locks

##### TEMPERATURE RECORDING OPTION

- ☐ USB port

##### VOLTAGE

- ☐ 120 V  
☐ 230 V

##### DOOR LOCK OPTION

- ☐ Electronic Numeric Keypad

*NOTE: All cabinets are furnished with right hand hinge. Door swing is reversible during installation.*

Item \_\_\_\_\_

Location(s) \_\_\_\_\_

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## Step 4: Transporting Warmed Units for Transfusion

1. Equipment: Use a "Red" Cambro heated rolling carrier pre-heated to maintain the 104°F (40.0°C) temperature during transport to the patient's location.
2. Urgency: Promptly transport the warmed unit to the patient's location to prepare for administration. Warmed units should not be returned to storage.

### HOT Transportation Storage

Once a unit enters HOT Transportation, it CANNOT be moved back into a HOT BANK storage WARMER.



## Step 5: Final Preparation & IV Administration

1. **Cool for Comfort:** Upon arrival at the patient's bedside, remove the unit from the transport carrier. Allow the unit to cool to 94°F (34.4°C). This is a specific recommendation from the University of Washington Medicine to ensure patient comfort, reduce pressure within the bag, and prevent patient excitement. Use a calibrated surface thermometer to verify the temperature.
2. **Final Verification:** While the unit is cooling, perform the final patient identification and product verification checks in accordance with the hospital's transfusion protocol.
3. **Hang Unit:** Once the product has reached 94°F, aseptically spike the bag and hang for IV administration.
4. **Monitor:** Monitor the patient throughout the transfusion process according to standard medical procedure.



### IV Administration

"Upon delivery, University of Washington Medicine staff recommend letting the SFWB cool to 94°F (34.44°C) for administration. We let the temperature drop for the patient's comfort. Heat can build pressure and lead to patient excitement." -Dr. FADM Bouck - USCG



This image shows a nurse or medical professional at President Biden's bedside, using a thermometer to ensure the Verdura Rx+ unit has cooled to the recommended 94°F (34.4°C) for patient comfort before administration.



## Step 6: Waste Disposal

Proper disposal of all materials is critical for safety and compliance.

- Packaging: Cardboard boxes, packing materials, and sterile outer wrappers can be disposed of in standard, non-hazardous waste receptacles, provided they are not visibly contaminated with biological product.
- Unused/Expired Product: All product bags (empty, partially used, or expired) and administration sets must be treated as Regulated Medical Waste (RMW).
  1. Place items in a designated red biohazard bag.
  2. Secure the bag and place it in the appropriate RMW container for collection and incineration.
  3. Follow all hospital-specific and local regulations for RMW disposal.

This image shows a medical professional in a designated utility or disposal area, properly disposing of the empty Verdura Rx+ bag and associated IV line into a red biohazard waste container, emphasizing adherence to safety and privacy protocols.





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Virus Treatment Centers

A handwritten signature in black ink, appearing to be "Cory Hofstad", written over a horizontal line.

<https://virustreatmentcenters.com>

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