**Shipping Blood Components and Products using J82/E38 Shipping Containers**

# PRINCIPLE:

# Most blood components and products are ordered directly by hospitals from Canadian Blood Services. Hospitals have the option of transferring blood components and plasma protein and related products between facilities for optimal utilization or to ensure best patient care. In such cases, it is necessary to ensure that the blood components and plasma protein and related products are properly packaged to maintain an acceptable temperature range during transportation, and the process ensures accurate tracking and disposition reporting.

Blood components or products being shipped for the purposes of redistribution, unless other agreements have been made:

* Red cells should have between 7 and 10 days of shelf life left prior to expiry
* Platelets should have between 12 and 24 hours of shelf life left prior to expiry
* Blood Products should have between 6 months of shelf-life prior to expiry
1. **PURPOSE:**

# To provide a standardized process for shipping blood components and/or plasma protein and related products to external sites using J82/E38 shipping containers, so that the acceptable temperature range is maintained during transportation and ensure accurate tracking and disposition reporting.9.1. This includes transfer for:

# Redistribution

# Provision of crossmatched units

# Provision of components during an MHP

# Transferring with a patient (also see IM007)

1. **RELEVANT REQUIREMENTS:**
	1. Blood components and plasma protein and related products must be visually inspected for abnormal appearance immediately before packing for transportation. This inspection must be documented.9.1,9.3
	2. Blood components and plasma protein and related products must be transported in a validated shipping container and in a manner that will maintain the storage temperature requirements specified by the supplier.9.1 Compliance with these specifications is acknowledged by the signed Memorandum of Understandingon file with ORBCoN / FCRP.
	3. Discontinuation of agitation of platelets during transportation should not exceed 24hrs. 9.1
	4. Shipping containers for blood components and plasma protein and related products must be constructed to resist damage, examined for damage prior to use and must be designed to include a tamper-proof seal.9.1, 9.4
	5. Shipping containers shall have an outer label that meets provincial, territorial, or federal transport regulations and identifies: 9.1,9.2
		* The shipping and receiving facility
		* That the contents are human blood components or plasma protein and related products
		* Any other cautions or descriptions
	6. All shipments of blood components and plasma protein and related products must include documentation that has the following information on shipping packing slip or issue voucher/form: 9.1, 9.2
* Name of shipping facility and receiving facility
* Identification of components or plasma protein and related products shipped (unit/lot numbers)
* Description of component/plasma protein and related product
* Total number of items shipped
* Date and time shipped
* Identity and signature of the person who packed the shipment
* A unique shipping document number to allow for traceability
* Indication if the blood component or plasma protein and related product is not intended for transfusion (e.g. sending for research purposes)
* Indication if the blood component or plasma protein and related product is quarantined (if applicable).
	1. All copies of shipping documentation must be retained according to requirements and/or facility policy, whichever is longest to maintain traceability of blood components and plasma protein and related products from their source until final disposition9.1 9.3
	2. Record of the storage temperature of the blood components or plasma protein and related products must be available on request.
1. **RELATED POLICIES/PROCEDURES (*policies in OTTRM*):**
	1. Glossary of Terms and Abbreviations
	2. [IM.003 - Visual Inspection of Blood Components and Plasma Protein and Related Products](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Ftransfusionontario.org%2Fwp-content%2Fuploads%2F2020%2F07%2FIM.003-Visual-Inspection-of-Blood-Blood-Components-and-Plasma-Protein-Products.docx&wdOrigin=BROWSELINK)
2. **MATERIALS:**
	* 1. **Specimen:** N/A
		2. **Equipment:** Approved and validated shipping container for redistribution of blood components or plasma protein or related products

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| **If shipping** | **Then use** | **And these materials** |
| **Refrigerated Blood Components (1-10C)****or** **Plasma Protein and Related Products (2-25C)** | **J82 Shipping Container** | * + 1x ice pack (8”w x8”h x1.5”d)
* 2x 4lb gel packs (10.5”w x 9.5”h)
* Plastic zip lock bags for gel and ice packs
* 2x Corrugated cardboard dividers (7.5”w x 7.5”h)
* Clear plastic over-wrap bag for product
* Clean crumpled paper
* Tamper-proof seal
* Purolator Healthcare Indicator label(if applicable)
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| **Room Temperature Blood Components (20-24C)** **or****Plasma Protein and Related Products (19-25C)** | **E38 Shipping Container** | * 3x 4lb gel packs (10.5”w x 9.5”h)
* Plastic zip lock bags for gel packs
* Clear plastic over-wrap bag for product
* Clean crumpled paper
* Tamper-proof seal
* Purolator Healthcare Indicator label(if applicable)
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* + 1. **Reagents:** N/A
		2. **Supplies/Related Forms:**
* [Plasma Protein Product Acceptable Shipping/Storage Requirements by Product as Per Manufacturer](https://transfusionontario.org/en/plasma-protein-product-acceptable-shipping-and-storage-requirements/)
* [Packing Configuration of J82/E38 Shipping Containers](https://transfusionontario.org/wp-content/uploads/2020/06/Packing-Configuration-for-J82_E38-Shipping-Containers.pdf)
* [Annual Shipping Container Temperature Verification Report](https://transfusionontario.org/wp-content/uploads/2022/12/Sept-2022.pdf)
* [IM.006F1 – Inter-Hospital Redistribution Form](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Ftransfusionontario.org%2Fwp-content%2Fuploads%2F2020%2F07%2FIM.006F1-Inter_Hospital-Redistribution-Form.docx&wdOrigin=BROWSELINK)
* [IM.006F2 Shipping Address Label](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Ftransfusionontario.org%2Fwp-content%2Fuploads%2F2020%2F06%2FIM.006F2-Shipping-Address-Labels.docx&wdOrigin=BROWSELINK)
* [IM007F1 – Inter-hospital Transfer Form – Blood Components/PPRP Accompanying a Patient](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Ftransfusionontario.org%2Fwp-content%2Fuploads%2F2020%2F07%2FIM-007F1-Inter-hospital-Transfer-Form-Blood-Components_Products-Accompanying-a-Patient-5.docx&wdOrigin=BROWSELINK)
* [IM007F2 – Shipment of Blood Components/Products Accompanying a Patient Shipping Label](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Ftransfusionontario.org%2Fwp-content%2Fuploads%2F2020%2F07%2FIM-007F2-Shipment-of-BloodComponents-Accompanying-a-Patient-1.docx&wdOrigin=BROWSELINK)
* Way bill (if required)
1. **QUALITY CONTROL/ASSURANCE:**
	1. Periodic verification of the shipping container shall be performed to confirm that temperatures remain consistent within the acceptable temperature range under the local conditions. Refer to ORBCoN’s Annual Shipping Container Temperature Verification Report. See Procedure Note 8.1.
	2. Shipping containers must be inspected before and after each use.

Check that:

* + The inner container is clean and free of breaks or cracks
	+ The straps and buckles are in good condition
	+ The outer container is free of breaks/rips
	+ Address labels from previous shipments have been removed
	+ Gel and ice packs are not cracked or leaking

**Note:** Discard any materials deemed unacceptable for use and inform supervisor

* 1. The acceptable shipping temperatures for blood components or plasma protein and related products are as follows: 9.1,9.2

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| **PRODUCT** | **SHIPPING TEMPERATURE** |
| Red Blood Cell Units | 1 - 10ºC (within 24 hours)9.2 |
| Platelets | 20 - 24ºC |
| Thawed Plasma | 1 - 10ºC (within 24 hours)9.2 |
| Plasma Protein and Related Products | See [Plasma Protein Acceptable Shipping and Storage Requirements](https://transfusionontario.org/en/plasma-protein-product-acceptable-shipping-and-storage-requirements/) |

1. **PROCEDURE:**

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| **Steps** | **Work Instructions** |
| 7.1 Inform Receiving Site  | ***Note:*** *If the maintenance of minimum inventory depends on the arrival of replacement products from the blood supplier, avoid shipping “near to expire” products until the new shipment has been received*. |
| **FOR BLOOD COMPONENTS** |
| 1. Inform receiving facility by phone and/or fax at least one day prior to redistribution to advise on the number of units being shipped and the approximate arrival time. Notify the receiving facility as soon as possible if the shipment is urgent e.g., short expiry date.
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| **FOR PLASMA PROTEIN PRODUCTS** |
| * + 1. When products have been identified by the site to be redistributed, then ORBCoN or FCRP will contact other facilities to see where the products can be used prior to expiry.

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| **If**  | **Then** |
| ORBCoN facilitates the redistribution | * ORBCoN will contact the facility that has the product to be redistributed to indicate where the product will be shipped to.
* The facility has to indicate the best pick up date and time (excluding Fridays and weekends) to have the product picked up, and where in the facility the products will be picked up.
* ORBCoN will make the arrangements with the courier for pickup and delivery.
* Shipping documentation will be sent electronically to the shipping facility along with packing instructions.
* ORBCoN will inform the receiving facility on the number of plasma protein or related products being shipped and the approximate arrival time and date.
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| FCRP facilitates the redistribution | * FCRP will contact the shipping facility and indicate where the product should be sent and date it should be sent on.
* FCRP will provide courier account information along with packing instructions and shipping documentation electronically to shipping facility.
* The shipping facility will make the arrangements for pick up through the designated courier provided by FCRP
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| 1. Pre-condition gel pack(s) and/or ice pack(s).
 | 1. Determine what materials need to be pre-conditioned
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|  | **J82 Container** | **E38 Container** |
| **Gel pack(s)** | Between 2ºC and 6ºC for at least 6 hrs. | Between 20ºC and 24ºC for at least 6 hrs. |
| **Ice pack(s)** | Between -25ºC and - 40ºC for at least 6 hrs. | N/A |
| 1. Prepare Shipping Container
 | 1. Determine which shipping container and configuration can be used to ship the components or plasma products.

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| ***If*** | ***Then*** |
| *Plasma Protein Products* | Select the shipping container acceptable for the shipping temperature range for the product. Refer to the Plasma Protein Product Acceptable Shipping/Storage Requirements by Product as Per Manufacturer .  |
| *Components* | Select the shipping container acceptable for the shipping range of the component. Refer to section 6.3. |

* + 1. Retrieve shipping container and all required supplies for the selected shipping container. Refer to section 5.2 for materials, supplies and packing configuration requirements. See procedure note 8.2.

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| ***If***  | ***Then*** |
| Shipping using the J82 container | Refer to the packing configuration for the maximum number of units that can be placed in the shipping container. Do not overfill. |
| Shipping using the E38 container | Refer to the packing configuration for the maximum number of units that can be placed in the shipping container. Do not overfill. |
| Label each shipping container with “Do Not Refrigerate – Keep at Room Temperature.” |

7.3.3 Examine the shipping container and material to be used. Refer to section  6.2. |
| * 1. Packing Component or Plasma Protein and Related Product for Shipping
 | * + 1. Pack any blood components or plasma protein and related products for shipping **within 1 hour** of courier pick up to ensure that acceptable temperatures are maintained for the duration of the shipment.
		2. Obtain the blood components or plasma protein and related products to be shipped from the storage area.
		3. Perform a visual inspection of the products. See [IM.003 - Visual Inspection of Blood Components and Plasma Protein and Related Products](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Ftransfusionontario.org%2Fwp-content%2Fuploads%2F2020%2F07%2FIM.003-Visual-Inspection-of-Blood-Blood-Components-and-Plasma-Protein-Products.docx&wdOrigin=BROWSELINK)
		4. Follow facility specific instructions for documenting the redistribution or transfer of blood components plasma protein and related products in the lab information system (LIS) or manual system. See Procedural Note 8.3.
		5. Complete Section A and B of Form [IM 006F1](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Ftransfusionontario.org%2Fwp-content%2Fuploads%2F2020%2F07%2FIM.006F1-Inter_Hospital-Redistribution-Form.docx&wdOrigin=BROWSELINK) if redistributing, use Form [IM007F1](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Ftransfusionontario.org%2Fwp-content%2Fuploads%2F2020%2F07%2FIM-007F1-Inter-hospital-Transfer-Form-Blood-Components_Products-Accompanying-a-Patient-5.docx&wdOrigin=BROWSELINK) if transferring with a patient.
		6. Make a copy of the completed form.
		7. Retain the copy in the laboratory for specified amount of time according to facility specific documents and record retention policy.
		8. Place blood components or plasma protein and related products in a plastic bag.
		9. Follow the packing configuration chosen in step 7.4.1 to place products in container
		10. Place extra security seal in the container per unit if shipment is for a patient transfer.
		11. Place temperature monitoring device inside the container prior to closing. (If applicable)
		12. Fill any dead air space with loosely crumpled paper to reduce the likelihood of movement, while still allowing air to circulate within the container.
		13. Place Styrofoam lid to close.
		14. Close the outer cardboard container and fasten the strap securely

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| ***If***  | ***Then*** |
| Shipping via Purolator | * Check the shipping label created for Purolator for correct shipper information and receiver information
	+ If shipping information is incorrect notify the person who arranged the shipment with Purolator to rectify.
* Place the original shipping documents first inside the plastic pouch.
* Then add the Purolator shipping label on top, so that it is visible for Purolator to scan.
* Ensure the Purolator Health Indicator label is affixed to the outside of the shipping container.
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| All other courier | * Complete [IM006F2.](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Ftransfusionontario.org%2Fwp-content%2Fuploads%2F2020%2F06%2FIM.006F2-Shipping-Address-Labels.docx&wdOrigin=BROWSELINK)
* Place the original shipping documents first inside the plastic pouch.
* Then, place the completed IM006F2 form inside the plastic pouch so that the receiving address is visible to the courier.
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| Shipping with a Patient | * Complete [IM007F2.](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Ftransfusionontario.org%2Fwp-content%2Fuploads%2F2020%2F07%2FIM-007F2-Shipment-of-BloodComponents-Accompanying-a-Patient-1.docx&wdOrigin=BROWSELINK)
* Place the original shipping documents first inside the plastic pouch.
* Then, place the completed IM007F2 form inside the plastic pouch, so that the information is clearly visible for the personnel going on the transfer.
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| 1. Apply Security Device/ Seal
 | 1. \****IMPORTANT***\*Apply the tamper-proof seal around the buckle of the strap so that the box cannot be opened unless the seal is removed.
2. Ensure there is no tail that can be caught in a sorting machine, if applicable. Cut any extra material that may get caught in a sorting machine.
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| 1. Prepare for pick up
 | 1. Place shipping container with completed documents in designated courier pick-up area where courier can retrieve easily, or contact the clinical care area where the patient is located if for transfer with a patient
2. Reconfirm that the tamper-proof seal is visible and intact.
3. Notify courier that shipment is ready for pick up, if required.
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1. **PROCEDURE NOTES:**
	1. If sites precondition the ice packs at different temperatures than stated in step 7.2, then those sites will need to perform their own validation to show that the containers can maintain acceptable temperatures for an established duration of time and provide the results to those sites that may receive the containers with products inside. [Refer to Redistribution Toolkit section 6](http://transfusionontario.org/en/download/provincial-redistribution-program-for-transfusion-services-in-ontario/)
	2. Where applicable, confirm with the courier that the shipping container can be transported inside the cab of the vehicle to ensure the container will not be exposed to extreme temperature.
	3. The shipping facility is responsible for the final disposition of blood components and plasma protein and related products in their LIS and reporting to CBS for items that have been wasted in transit.
2. REFERENCES:
	1. CSTM/SCTM Standards for Hospital Transfusion Services v5. CSTM Markham, December 2022, 5.7.1 Transportation, 5.1.1.3, 5.1.1.4.
	2. CSA Z902-20 Canadian Standard for Blood and Blood Components; March 2020, 9.5
	3. Blood Regulation SOR/2013-178. Minister of Justice; August 25 2020, http://laws-lois.jstice.gc.ca
	4. IQMH (Accreditation Canada Diagnostics) Medical Laboratory Accreditation Requirements v8 Dec 2019.
3. REVISION HISTORY

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| Revision Date | Summary of Revision |
| Aug 2014 | * Revised name of manual
* Changed title of document to include shipment of blood components
* Revised sections 1.0, 4.0 & 5.0
* Revised and renumbered sections 2.0, 6.0 & 8.0
* Added *Reporting* as section 7.0
* Updated list of references to include most recent editions
* Revised list of appendices
 |
| Nov 2017 | * Revised title of document.
* Revised sections 1.0, 4.0,6.0, 9.0, 11.0 to ensure compliant with updated Standards
* Added procedural note 8.5
* Revised list of references to reflect current standards.
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| Feb 2018 | * Added step 6.8.6 completing the shipping label
 |
| Mar 2021 | * Updated references
* Updated IM006F to include contact email
 |
| Oct 2022 | * Addition of Policy
* Rewording of all sections
* Updated references
* Removal of appendices
* Addition of links
 |
| March 2023 | * Addition of information for transfer with a patient
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