

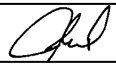


**Document History:**

**Title:** Issuing Plasma Protein Products(Derivatives)/ Return within a Facility Previously Issued Plasma Protein Products (Derivatives)

**Site(s):** All DSM TM sites

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**Approved by:** Dr. Charles Musuka      **Written By:** TM Discipline Team  
 Signature:    
 Date: 21-JUN-2017      Date: MAR-2011

#	Details of Revisions:	Approval:	Date:
1	New document	A Kabani	31-MAR-2011
2	4.1 and 4.2 added note for Trace Line sites to refer to Trace Line procedures	C Musuka	05-NOV-2012
3	4.1.7 c) refer to procedural note 6.5	C Musuka	10-DEC-2013
4	4.1.3 added bullet refer to inv procedure for issuing SCIG and C1 Esterase	C Musuka	04-JAN-2016
5	Modify the name Derivatives to plasma protein products to maintain constancy with CBS	C Musuka	31-JAN-2017
6	<ul style="list-style-type: none"> <li>• 2.2 to 2.5 new scopes</li> <li>• 3.0 added forms</li> <li>• 4.1 revised and expanded steps throughout</li> <li>• 6.1 and 6.2 new previous renumbered and 6.3 revised and expanded throughout</li> </ul>	C Musuka	21-JUN-2017
	<ul style="list-style-type: none"> <li>• 2.2 revised to reflect IVIG process effective July 2017</li> <li>• 2.5 revised to reflect process effective July 2017</li> <li>• 2.6 new</li> <li>• 3.0 updated with correct names of IVIG/SCIG request forms</li> <li>• 4.1.2.1 revised and note removed to reflect process effective July 2017</li> <li>• 6.1 and 6.2 revised to reflect process effective July 2017and with correct request forms</li> </ul>		

# Issuing Plasma Protein Products (Derivatives)/Return of Facility Previously Issued Plasma Protein Products (Derivatives)

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## 1.0 Principle

See INV procedure- Issuing of blood, blood components and derivatives/ handling returned issued product within a facility

## 2.0 Scope and Related Policies

- 2.1** See INV procedures- Issuing of blood, blood components and derivatives handling returned issued product within a Facility  
 - Plasma protein products (derivatives) for Home Infusion Programs
- 2.2** Trace Line testing sites and/or Trace Line hub sites shall provide plasma protein products (derivatives) to non-Trace Line sites they service.
- All IVIG will be:
    - Patient specific – cannot be issued to another patient
    - Labelled with lot#, product code and sequence#, patient demographics along with Record of Transfusion (ROT)
  - Other PPP (derivatives), except RhIG, will have DSM 104 tag attached with lot#/product code/sequence#
  - RhIG will have treatment slip attached with lot#/product code/sequence #
- 2.3** Trace Line testing sites and/or Trace Line hub sites shall provide plasma protein products (derivatives) for Home Program patients to the non-Trace Line sites they service:
- Product will be labelled with Lot#, product code and sequence #, patient demographics along with ROT
  - Products that are patient specific and cannot be issued to another patient
  - Includes emergency stock, if required, to be available for Home Program patient
  - Following issue, fax confirmation for Home Infusion Programs form must be completed by issuing site and faxed to appropriate Home Program
  - ROT(s) are provided to patient at time of issue:
    - Following issue to patient clearly indicated issue date/time on ROT(s)
    - Final disposition may be confirmed upon issue (transfused, e.g. presume transfused) for **Home Program ONLY**
- 2.4** If emergency stock for Home Program patient is to be available at facility blood bank/BTS:
- Ensure dose required is available and reserved for patient
  - Rotate stock when regular dose is received
  - If product is within 60 days of expiry contact Clinical Home Infusion Program to determine if product can be sent to another facility

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## 2.0 Scope and Related Policies cont'd

- 2.5** A completed IVIG/SCIG physician request initial treatment form shall be received or in effect for one time or multiple infusion IVIG and SCIG requests:
- IVIG/SCIG cannot be issued until completed Initial Treatment form is received at Blood Bank/BTS
  - For patients on multiple infusions with clinical indication of Primary Immune Deficiency (PID) and being managed by physicians at Allergy Clinic Winnipeg only Initial Treatment form is required and patients are exempt from further follow up evaluation
  - For patients on multiple infusions with other clinical indications or clinical indication of PID and not being managed by physicians at Allergy clinic Winnipeg, a follow up evaluation will be required every 6 months during treatment:
    - Completion of the IVIG/SCIG physician request Follow Up form by the physician managing the patient is required
    - IVIG/SCIG cannot be issued until required completed Follow Up form is received at blood bank/BTS
    - A site specific IVIG/SCIG log/file can be maintained by blood bank/BTS to manage date when subsequent completed Follow Up forms must be received, if applicable
    - Trace Line sites will manage when 6 month evaluation required by entering in Trace Line, expiry date of IVIG/SCIG Physician Request Initial Treatment and/or Follow Up forms in Patient file >Protocol tab>Observations field
  - Copy of completed IVIG/SCIG Physician Request Initial Treatment and/or Follow Up form shall be faxed to Blood Management Service (BMS) at 204-940-3255 with original retained by blood bank/BTS
  - Trace Line testing/hub sites that issue IVIG/SCIG to non-Trace Line sites shall be responsible for maintaining and faxing to BMS the completed IVIG/SCIG Physician Request Initial Treatment and/or Follow Up forms
- 2.6** Only approved prescribers can request IVIG/SCIG. List of approved prescribers shall be available to blood bank/BTS on:
- Best Blood Manitoba website
  - Any Trace Line terminal For Trace Line sites:
    - Computer>MB Trace Line reports on ([\\winfls](#)) (L:)

## 3.0 Materials

See INV procedures- Issuing of blood, blood components and derivatives handling returned issued product within a facility

- Plasma Protein Products (Derivatives) for Home Infusion Programs

Fax Confirmation for Home Infusion programs form (F160-INV-26a)

Intravenous Immune Globulin (IVIG) Subcutaneous Immune Globulin (SCIG) Physician request Initial Treatment and/or Follow Up forms

## 4.0 Procedure

### 4.1 Procedure for issuing plasma protein products (derivatives)

**Note:** For Trace Line sites refer to Trace Line procedure- Issuing of Plasma Protein Products (Derivatives) in Trace Line to: Patients within a Facility/Home Program Patients

- 4.1.1** Plasma protein products (derivatives) can only be issued immediately prior to the patient being transfused or patient pick-up in order to maintain proper storage.
- 4.1.2** When the plasma protein product (derivative) is required for infusion the following information on applicable facility patient request/patient information form must be brought to the blood bank/BTS:
- Patient's last and first name/ patient's PHIN/PHN or unique identifier
  - Type of plasma protein product(s) required
  - Number of vials/dose/volume required
- 4.1.2.1** For IVIG/SCIG the Trace Line testing site or Trace Line hub site that issued the IVIG/SCIG to the non-testing site is responsible to ensure the completed IVIG/SCIG Initial Treatment and/or Follow Up form has been received/is not expired. Refer to procedural notes 6.1 and 6.2
- 4.1.3** Retrieve requested plasma protein products (derivatives) from the appropriate controlled storage area.
- Plasma protein products (derivatives) received as stock from Trace Line testing site or Trace Line hub site will have Trace Line generated and DSM 104 tag attached with product information.
    - Patient information will be completed on tag at time of issue
  - Plasma protein products (derivatives) received from Trace Line testing site or Trace Line hub site for IVIG and Home program patients will be labelled specific for patient with Record of Transfusion (ROT).
    - These are patient specific and cannot be issued to another patient
  - If Plasma protein products (derivatives) was received directly from BPM at CBS Refer to procedural note 6.8
- 4.1.3.1** If product is received from Trace Line testing/hub site verify the following information on product to tags/labels attached to vial (also to ROT for IVIG and Home program patient products)
- Derivative type
  - Lot number/sequence number
  - Expiry date
- Note:** Resolve discrepancies before products are issued
- 4.1.3.2** Refer to the following procedures and procedural notes for additional information regarding issuing:
- Procedural note 6.3: Issuing PPP (derivative) for transport with a patient
  - Procedural note 6.4: Issuing PPP (derivative) to Home Program patient
  - Procedural note 6.5: Issuing Rh immune globulin to an authorized health care provider or clinic
  - Procedural note 6.6: Issuing PPP (derivative) as stock to another facility
  - INV Procedure Plasma Protein Products (Derivatives) for Home Infusion Programs
- 4.1.4** Perform visual inspection of each product. Refer to INV procedure: Visual Inspection of blood, blood components and plasma protein products
- 4.1.5** If DSM 104 tag only is attached; complete DSM 104 tag and compare to the information on the request form/patient information form:
- Patient's last and first name, letter by letter
  - Patient's PHIN/PHN or unique identifier, character by character

### 4.0 Procedure Cont'd

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**4.1. Cont'd**

**4.1.6** Obtain appropriate blood bank log and locate plasma protein product (derivative) lot number, sequence number (if applicable) and complete the following information in appropriate column

a) **Patient information:**

- Patient's last and first name
- PHIN/PHN or unique identifier
- Patient location

b) **Issuing information:**

- Date and time (use lab clock)
- Visual inspection
- **Full** last name of the issuer (print or legibly sign). For use of initials, refer to procedural note 6.7

c) **Transporter information:**

- **Full** last name of the transporter (print or legibly sign) in the "Transporter" column if applicable.

**4.1.7** Issue the plasma protein product (derivative) to the transporter

*Note: For issue to Home Program Patient refer to procedure note 6.2*

**4.1.7.1** Provide the transporter with request form and with the transporter verify the following

- Patient's last and first name
- PHIN/PHN or unique identifier
- PPP (derivative) being issued matches request
- Patient location

**4.1.7.2** Complete the following on the request form

- Blood bank/lab staff to sign/initial beside: Issued by
- Transporter to sign/initial beside: Transporter
- Time stamp/complete beside: date and time

**4.1.7.3** Place PPP (derivative) in plastic bag and issue to transporter

**4.1.8** If the plasma protein products (derivatives) are being shipped to another facility then package for transport. Refer to INV procedure Inter-facility shipping of blood, blood component or plasma protein product.

**4.1.9** Retain in blood bank completed request form and copy of all appropriate forms.

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## 4.0 Procedure Cont'd

### 4.2 Procedure for returning plasma protein products (derivatives) to inventory

**Note:** For Trace Line sites refer to Trace Line procedure- Handling in Trace Line: Returned Previously Issued within facility blood, blood Components and derivatives

**4.2.1** Document date and time of return and initial of person returning product in blood bank log and on tag/ROT (if applicable).

**4.2.2** Visually inspect the product(s) to ensure the following criteria are met prior to returning plasma protein products (derivatives) to inventory:

- The vial closure has not been disturbed
- The plasma protein product (derivative) has not been out of controlled storage for longer than the acceptable time period

**Note:** If product has been out of controlled storage longer than acceptable time; check with TM Physician on call and senior or charge technologist to determine if product should be discarded. Some exceptions may be allowed.

**4.2.3** Return the plasma protein products to appropriate controlled storage if above conditions are met.

**4.2.4** Discard the plasma protein products if the above conditions are not met.

- Document final disposition (discarded) including reason in blood bank log
- Refer to INV procedure- Documenting the Final Disposition of Discarded blood, blood Components and plasma protein products

## 5.0 Reporting

**5.1** Ensure all required information is completed on request/patient information form

**5.2** Ensure appropriate blood bank log is completed with all required documentation

**5.3** Ensure "Fax Confirmation for Home Infusion Programs" form is completed and faxed to applicable Clinical Home Infusion Program

## 6.0 Procedural Notes

**6.1** Upon receipt of request for IVIG the blood bank/BTS must ensure:

- Ordering physician is on the list of approved prescribers to order IVIG/SCIG
- Completed IVIG/SCIG physician request initial treatment form has been received
- If required completed subsequent IVIG/SCIG Physician Follow Up form has been received at required intervals
- Completed IVIG/SCIG Physician Request Initial Treatment and/or Follow Up form is faxed to Blood Management Service (BMS) at 204-940-3255 with original retained by Blood Bank/BTS

**Note:** The Trace Line testing site or Trace Line hub site that will be issuing the product must receive and is responsible for maintaining and faxing to BMS the completed IVIG/SCIG Physician Request Initial Treatment and/or Follow Up forms

**6.2** If it is determined that completion of the IVIG/SCIG Physician Initial Treatment and/or Follow Up form from is required, the Blood Bank/BTS must fax form to requesting Physician and IVIG cannot be issued to patient until completed form is received

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**6.0 Procedural Notes Cont'd**

**6.3 Issuing plasma protein product (derivative) for transport with a patient:**

- Refer to INV procedure- Inter-facility shipping of blood, blood component or plasma protein product
- Record name of facility being transferred to in appropriate blood bank log

**6.4 Issuing factor concentrates/C1 Esterase/SCIG to Home Program patients:**

- 6.4.1** The product will have already been shipped to the designated facility:
- If received from BPM at CBS the initials of the patient's last and first name, PHIN/PHN or unique identifier, factor concentrate name and amount ordered should be documented on the blood supplier packing slip.
  - If received from Trace Line testing site and/or Trace Line hub site product will have Trace Line generated tag and be labelled specific for patient with Record of Transfusion (ROT). These are patient specific and cannot be issued to another patient
- 6.4.2** Obtain "*Fax Confirmation for Home Infusion Programs*" form and complete the patient/product information
- 6.4.3** Obtain identification form the patient/proxy and verify it against request form when they arrive
- 6.4.4** Retrieve product
- 6.4.5** Issue plasma protein products:
- Ask patient (or parent/guardian) to sign as the transporter
- 6.4.6 Home programs ONLY** Provide patient with copy of ROT(s)
- Instruct patient that if any vial is not transfused and discarded to document lot#, sequence# of vial and provide this information to Blood Bank when they return to pickup next dose. This information then needs to be sent to issuing Trace Line site to update disposition in Trace Line
  - Indicate issue date/time on ROT(s)
  - Send ROT(s) to issuing Trace Line site for completion of final disposition in Trace Line
  - Final disposition may be confirmed as Transfused (presumed Transfused) upon issue
- 6.4.7** Following issue to patient fax the completed "*Fax Confirmation for Home Infusion programs*" form to appropriate Home Program

**6.5 Issuing Rh immune globulin to an authorized health care provider or clinic:**

- Obtain the patient's last and first name and PHIN/PHN or unique identifier
- Record patient information in the appropriate blood bank log at the time of issue
- Record name of facility being transferred to in appropriate blood bank log
- Refer to INV procedure- Inter-facility shipping of blood, blood component or plasma protein products

**6.6 Issuing plasma protein product (derivative) stock to another facility:**

- Prepare and attach plasma protein product tags for each vial of plasma protein product
- Refer to INV procedure- Inter-facility shipping of blood, blood component or plasma protein product
- Record name of facility being transferred to in the appropriate blood bank log

**6.7** Initials of the individuals who issue blood, blood components or plasma protein product may only be used if an initial log of all employees who issue or transport blood, blood components and plasma protein product is maintained and updated regularly.

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**6.0 Procedural Notes Cont'd**

**6.8** To promote traceability, it is ideal that all Plasma Protein Products (Derivatives) are tracked in Trace Line. non-Trace Line sites shall order from designated Trace Line site and not directly from BPM (CBS) whenever possible

**6.8.1** If plasma protein products (derivatives) to be issued were received directly from BPM (CBS), if possible: **do not** issue to patient and proceed to:

- Order replacement stock from designated Trace Line site
- Upon receipt of replacement product ship PPP (Derivatives) received directly from BPM (CBS) to designated Trace Line site for entry in Trace Line

**6.8.2** If PPP (derivatives) received directly from BPM **must** be issued to patient proceed to:

- Attach DSM 104 tag to vial
- Complete with appropriate product information/lot number/expiry date.