Deviation From SOP

Date: 03/12/22

Affected SOPs: _Dispense and Return BBCP -18 and new form Product Dispense Verification

Description:
Due to repeat FDA reportable errors related to dispensing blood products, we need to make an immediate update to the SOP and add a form to document the dispense process. This has been validated with team members as an appropriate corrective action. This process will document the dispense steps and verify the information against the product and product order.

Summary of Changes:
1) Revision to BBCP-18 to match with the addition of the new form.
2) New form Product Dispense Verification

Implementation of Change
This change management had been started and impact assessment completed with BB Leadership. The change. The impact assessment has been completed (owner, T.Ingle).

The team will be notified via email, and trained via Medtraining and Huddle review. This will be started 3/18/22 with full implementation and completion of training by 3/28/22 for all team members.

The SOP and form changes will be placed in Policy Tech, when available.
In the meantime the form and revised SOP will be available hard copy in the Standard Work book, and available electronically in TEAMS.

Jayanna Slayten

BB Supervisor
Jayanna Slayten, MS, MT(ASCP)SBBcm

Approved By: BB Medical Director

DRAFT VERSION 3.18.22

Indiana University Health

Origination:	*03/2005*
Effective:	*04/2020*
Last Approved:	*03/2020*
Last Revised:	*03/2020*
Next Review:	*03/2022*
Owner:	*Jessica Isaac: Executive Director-Lab-Academic Health Center*
Area:	*Lab - Blood Bank*
Tags:	*Manual: Blood Bank Testing*
Applicability:	*Indiana University Health Pathology Laboratory*

Dispense and Return Products

PURPOSE:

To detail procedure for dispensing and returning blood products from Blood Bank via Pneumatic tube or nursing pickup. This procedure is performed after components have been crossmatched and/or assigned to the patient and a Transfusion Document is attached to the component, and a Delivery request has been entered.

SCOPE:

This SOP details procedure for all blood products dispensed and returned by IU Health Blood Bank personnel. MT-I, MT-II, Sr. Lab Assistants, and Lab Assistants are impacted by this procedure.

EXCEPTIONS:

Exceptions to this procedure must be approved by the Blood Bank Medical Director, Supervisor or Manager.

DEFINITIONS:

None

POLICY STATEMENTS:

1. Dispensed after Blood Bank has received Verbal or Written request from Ward to **TRANSFUSE**, per physician order.
   Exceptions:
   1. Trauma: Massive transfusion protocol (MTP), BBCP-015.
   2. Uncrossmatched: BBCP-19 Emergency Uncrossmatched Blood Requests
2. Nursing personnel must identify patient by: **Full Name** and **MRN** (Medical Record Number), Component type and number of units (may be in mLs).
3. ALL products are INSPECTED immediately prior to dispensing.
4. Products failing inspection criteria cannot be dispensed.
5. All products are dispensed with packing slip containing: Unit Number and intended recipient.

6. All products returned to Blood Bank are INSPECTED and returned to inventory upon meeting satisfactory inspection criteria. Products **not** meeting satisfactory inspection criteria will be placed in quarantine for resolution.
7. Acceptable temperature of returned units is 1 to 10 C.
8. Units returned with temperature > 10 C or > 30 minutes from dispense time and meets all other visual inspection criteria may be reissued to the intended recipient provided that the transfusion is completed within 4 hours of the initial dispense time for the intended recipient.
9. When available: Patient's blood products will be dispensed in the following order:
   1st Autologous units.
   2nd Directed units.
   3rd Allogeneic units.
10. All blood products dispensed through the pneumatic tube system must have two foam inserts.

PRINCIPLE/BACKGROUND:

None

MATERIALS:

None

11. The tech who assigns or crossmatches a unit should not dispense the product, whenever possible.
12. The implementaiton of the Product Dispense Verification form should aid in preventing dispense issues.

SPECIMEN REQUIREMENTS:

None

PROCEDURE:

1. The following types of orders are accepted:
   1. Computer-generated request: A printout is generated automatically in the laboratory, routed to a printer that is designated for orders.
   2. Phone orders: The team member receiving the order should complete all fields of the Telephone - Component Request form (see Attachment 1).
   3. Written requisitions: Paper requisitions are sometimes submitted to the laboratory.
2. All requests verbal or written must include:
   1. Patient's First / Last name and MRN.
   2. Type and number of blood components
   3. Location blood is to be sent to. (e.g. Pneumatic tube station number)
   4. Verbal orders must include caller's name.
3. Prepare cooler if indicated, see SOP Transport Cooler Management – Wet Ice or Transport Cooler Management – Utek Cool Pak to prepare the coolers for use. **NOTE:** Skip this step for blood products to be sent via pneumatic tube.
4. Remove blood product(s) from storage.
5. Review Transfusion Document attached to the product and compare with the computer-generated order, written order, PPI screen, and/or Telephone - Component Request.

1. Verify that the intended recipient's name and MRN, ABO group, and Rh type on the Transfusion Document matches the order or PPI screen.
2. Verify that the DIN, Donor ABO group, and Rh type on the Transfusion Document matches the blood component label.
3. If the patient blood type and the component blood type are not identical, verify that a **Donor Type Differs sticker** is present and is initialed.
4. For Red Blood Cell products, verify that a crossmatch interpretation is provided. If the crossmatch interpretation is "Least incompatible", verify that the order states that Least Incompatible units are acceptable.
5. Volume - if a specific volume is ordered and prepared, verify that the component contains the volume requested (re-weigh or verify volume in syringe) and that the label matches the contents of the aliquot.
6. Special transfusion requirements.
   NOTE: Special Transfusion requirements may be listed in the Precautions section of a Cerner-generated order. Review the Precautions on the Cerner-generated order carefully and add any Transfusion Requirements to the patient's PPI following Patient Product Inquiry.
   1. Review the order/PPI for an Irradiation Requirement. If present, verify that the component is Irradiated and verify that the Irradiated requirement is printed on the Transfusion Document.
   2. Review the order/PPI for a CMV requirement. If present, verify that the component is labeled as CMV negative and verify that the CMV Neg requirement is printed on the Transfusion Document.
   3. Review the order/PPI for antigen-negative requirements. If present, verify that the component has an antigen typing tag, that the appropriate antigen is marked as "neg" or "0", and that the antigen-negative attribute is printed on the Transfusion Document.
   4. Review the Cerner generated order/PPI for any group-specific instructions (i.e. Group O Red Cells or O Neg Red Cells). Verify that the component meets those indications as described.
   5. Verify the expiration date and time to ensure that the product is not expired.
   6. Verify that the date and time of issue matches the order's expected date and time.
6. Perform visual inspection of product(s). Note: Refer to the American Red Cross Blood Component Visual Inspection Guide

Criteria	Acceptable Conditions
Appearance	◦ Normal in color ◦ Free from clots and/or fibrin strands
Integrity	◦ Not leaking ◦ Ports sealed
Storage/ Temperature	The product(s) were stored in an appropriate device and the current temperature is acceptable.
Expiration	The product(s) are not expired If the product is within 4 hours of expiration, then communicate the shortened expiration time with the clinical staff. Document this communication on the Cerner

	generated order.
Labeling	The label and tag are complete, legible, and intact.

DO NOT dispense any product that does not pass visual inspection - quarantine any unacceptable products and consult management. **DO NOT** dispense any product which will expire within 4 hours without communication with the clinical staff.

7. Use Cerner function: "Dispense and Assign Products": For reference see SOP Dispense and Assign Products.
    1. Select your location.
    2. Select "Dispense" under "TASK".
    3. Type in patient's MRN, received from patient's ward. From "Telephone – Component Request" or "Deliver Blood Product (BB Deliver Blood Product)" slip.
        1. DO NOT use the Transfusion Document (TD) as the source of patient's identifying information.
        2. If patient has multiple encounters, highlight the correct encounter (FIN# is found on the requisition below the MRN), then click OK.
    4. Scan the DIN barcode of the blood product to be dispensed. If a window opens requesting that a component be selected, scan the product code to select the component.
    5. Repeat Step 7.4 for all components to be dispensed, then select ***"Save"***.
    6. Dispensing form will display on screen. Complete the required information:
        1. Visual inspection: Should be "OK" - unacceptable blood products should be quarantined and not dispensed.
        2. Reason: Select the most relevant reason, for example, Transfusion, Surgery, Emergency, ECMO, etc. icable reason.
        3. Courier:
            1. Units delivered by pneumatic tube: Enter the name of the person requesting blood and the tube station number.
            2. Units delivered by cooler: Enter the cooler number and expiration date/time.
            3. Units for MTP: Enter the MTP dose number, cooler number, and expiration time (and date if there is room).
            4. Location: Defaults to patient's current location. Type in patient's actual location, if applicable. i.e., MA5S, U5PE.
            5. Select ***"Enter"***
        4. Packing slip will print. Retrieve the Packing Slip from the printer and **confirm that the Packing Slip matches patient and product(s)**.
    7. If sending products via pneumatic tube (**NOTE:** if sending products via Cooler, follow Transport Cooler Management – Wet Ice or Transport Cooler Management – Utek Cool Pak):
        1. Place product(s) into biohazard bag.
        2. Place top copy of packing slip and product(s) into pneumatic tube.
            1. Do not place more than two products in a single tube.

2. Do not place 1-6°C products in same tube with 20-24°C products.
3. Do not send products for more than one patient in a single tube.

3. Place tube on launcher.
4. Select appropriate tube station number; Verify correct Station entered; Select "SEND" and verify tube destination is "Accepted".

8. Place ~~bottom copy~~ of packing slip on/in counter / file.

8a) Place the product order, delivery and Product dispense when the product is sent to the patient.
8b) The documenation will be audited on an routine basis.

9. When the signed top copy of packing slip is returned to Blood Bank, discard bottom /unsigned copy and file signed top copy appropriately. Retain the signed dispense slip.
   a. If top signed copy is not returned promptly, call nurse/ charge nurse or appropriate department and request it be returned.
   b. If the dispense is returned without signature and date/time, then contact the nurse/charge nurse or appropriate department. Return the dispense slip to their attention and ask for proper documentation.
   c. Signature and date/time is not required if:
      1. Dispense packing slip is returned with the blood product(s) and all blood product(s) listed on the dispense packing slip is returned to the blood bank.
   d. If there is not adequate contact person with the department receiving the products, then generate an external occurrence following the Deviation Documentation and Management.
10. When tube system is unavailable, nursing representative must come to Blood Bank, pick up blood product, and sign packing slip.

8. Returning products to inventory (Cerner "Return Products"): (See SOP Return Products)
   1. Perform visual inspection as in step 6.0.
   2. When Red Cells and/or Plasma are returned, affix a Hemo Temp on the product and allow to equilibrate.
   3. Use Cerner function "Return Products" to bring blood product back into inventory.
   4. Return reason: select appropriate response.
      1. *Not Used*
      2. *Order changed*
      3. *Patient has fever*
      4. *Patient refused*
      5. *Product expired*
      6. *Product warm*
      7. *Surgery done*
      8. *Surgery cancelled*
   5. Select the appropriate Visual Inspection choice from the choices listed: if you selected a reason other than "OK", the product will be quarantined.

Visual Inspection/ Temperature Acceptable	Visual Inspection/ Temperature Unacceptable

OK	*Bag Broken* *Discoloration* *Fibrin/Clot* *Hemolyzed* *Icteric* *Improper storage* *Product not returned* *Prod warm* *Unit warm*

6. Product Number: Scan the DIN barcode of the product being returned. If a window pops up prompting for a product selection, scan the product code label to select the product.
7. Confirm all information on screen is correct.
8. Complete **REQUIRED** fields "Temperature" and "Degrees"
    1. When using HemoTemps on Red Cells record "Temperature" displayed:
        1. **1-3** record: **3**
        2. **4-6** record: **6**
        3. **7-9** record : **9**
        4. **10-12** record: **12**
    2. "Degrees" Centigrade must always select from dropdown: **C**
    3. When Red Cells, Plasma, Platelets and/or Thawed Cryo is returned at close to room temperature (20 to 24 C) record: **RT**
    4. Select **"SAVE"**.
    5. Follow Return, Dispose and Wastage Job Aid BBCP-18.00 to complete the completion of the appropriate dispose and wastage for the product. SOPs BBCE-020 and BBT-072 may apply.
9. Only Technologists and Supervisors can release products in Cerner:
    1. Select the **"QUARANTINE PRODUCTS"** icon.
    2. Select **"Task"** from bar.
    3. Select **"Release Quarantine"**
    4. **"Product number":** Barcode **<ENTER>**
    5. **"Quarantine release reason":** Select reason.
    6. Select **"Add".**
    7. Confirm data.
    8. Select **"SAVE".**
10. Products dispensed and returned within temperature and meet all other visual inspection criteria may be reissued to the intended recipient but must be infused within 4 hours from original dispensed time:
    1. Use Cerner function "Return Blood Products".
        1. Return reason: "out of BB >30minutes.
        2. Visual Inspection: should be "OK".

3. Record "Temperature" and "Degrees" as in 6.4.5.

2. Modify the expiration date and time in Cerner, product, and TD to 4 hours from dispensing time.
    1. If the original expiration date and time of the unit is **AFTER** 4 hours from the dispensing time, modify the expiration date and time in Cerner, on the product and TD to reflect 4 hours from the dispensing time AND RE-LABEL the product with the new expirationtime.
        1. Example:
           Original expiration = 6/12/2013 @ 2359
           Original dispense time = 6/12/2013 @ 1400
           Then modify expiration to **6/12/2013 @ 1800**
    2. If the original expiration date and time of the unit is **BEFORE** 4 hours from the dispensing time, then **DO NOT** modify the expiration date and time in Cerner, on the product and TD.
        1. Example:
           Original expiration = 6/12/2013 @ 2359
           Original dispense time = 6/12/2013 @ 2100
           Then DO NOT modify expiration.
3. Unit can be re-dispensed to the originally assigned patient only.
    1. Product must not be expired and transfusion must be completed prior to expiration. Repeat the Dispense process from Step 1 of this procedure.
    2. Error correct the Dispense Packing List, which will pre-print with a transfusion completion time of 4 hours from the new dispense time, to reflect the time transfusion must be completed as the expiration date/time of the product.
4. If unit is not used, perform wastage process (see Final Disposition / Wastage).

1. Release product from assigned patient when order canceled or inventory management dictates.
   Use Cerner function: "Release Products" (see SOP Release Products).

APPENDICES/ATTACHMENTS/FORMS/LABELS:

Attachment 1:Example of Telephone – Component Request form

Return, Dispose, Wastage Job Aid BBCP-018.00

REFERENCES/CITATIONS:

Quality System, AABB/IU Health.
AABB Technical Manual, current edition.
AABB Standards, current edition.

Policy #:

BBCP – 018

Attachments

1: Example of Telephone – Component Request Form

Approval Signatures

Step Description	Approver	Date
CLIA Laboratory Director	Muhammad Idrees: Laboratory Director	03/2020
Medical Director/Division Director	Nguyet Le: Staff Physician	03/2020
Medical Director/Division Director	Daniel Smith: Staff Physician	03/2020
Endorsing on Behalf of Oversight Committee	Cynthia Watt: Project Coordinator	03/2020
Supervisors (QA Unit)	Evangeline Miguel: Supervisor-Lab	03/2020
Supervisors (QA Unit)	Tracie Ingle: Supervisor-Lab	03/2020
Supervisors (QA Unit)	Jayanna Slayten: Supervisor-Lab	03/2020
Director	Heather Vaught: Dir-Transfusion Medicine-Lab	03/2020

Applicability

IU Health Pathology Laboratory

Product Dispense Verification

Form Excluded for MTP and Emergency Release of Products

1) Are you the SAME team member who assigned or crossmatched this product?

Check mark or X	IF:	THEN:
	YES (Not working alone)	STOP. Find another team member to dispense product
	YES – working alone	Continue with Dispense
	NO	Continue with Dispense

2) Document information

Alternately: Place Patient Accession Sticker Here

Patient Name: _____

MRN: _____

3) Document unit being dispensed

Unit # _____

4) Did you pull the correct product for Dispense?

	YES	NO	If No, Resolution Step Completed and repeat step
Does the Component Type selected for dispense match the requested product on the Delivery?			

5) Review **Product Order** with Transfusion Document & Donor Unit.

	YES	NO	If No, Resolution Step Completed and repeat step
Does the product order match the unit? - Irradiated, CMV Negative (or equivalent) - Washed, Fresh or Ultrafresh (or acceptable) - Antigen negative, if appropriate - Correct product type (red cell, plasma, platelet or cryo)			

6) Document these Product Dispense Checks below and ensure all steps outlined in the Dispense and Return SOP are followed to dispense the product in CERNER.

	YES	NO	If No, Resolution Step Completed and repeat step
Patient Name and MRN match			
Transfusion Tag is Attached			
DIN and ABORH on Transfusion Tag matches Bag			
Type Differ Sticker is applied when applicable			
Product Code on Transfusion Tag matches the Bag			

7) Confirm Dispense Packing Slip matches Product when placing in Dispense Transport Bag

I have reviewed and confirmed all patient and donor unit information matches original product order and deliver blood product request. All transfusion requirements have been met prior to release of this product.

BB Team Member Initials_____ Date: _____

Indiana University Health
Indianapolis, IN 46202

Standard Operating Procedure Manual (SOP) – Transfusion Medicine

Form #: BBT-F 080.00
Manual: Testing
Original Effective: 03/18/22
Revised: ..... NEW
Revision Effective: NEW

Product Dispense Verification

Form Excluded for MTP and Emergency Release of Products

1) Are you the SAME team member who assigned or crossmatched this product?

Check mark or X	IF:	THEN:
	YES (Not working alone)	STOP. Find another team member to dispense product
	YES – working alone	Continue with Dispense
	NO	Continue with Dispense

2) Document information

Alternately: Place Patient Accession Sticker Here

Patient Name: _____

MRN: _____

3) Document unit being dispensed

Unit # _____

4) Did you pull the correct product for Dispense?

	YES	NO	If No, Resolution Step Completed and repeat step
Does the Component Type selected for dispense match the requested product on the Delivery?			

5) Review **Product Order** with Transfusion Document & Donor Unit.

	YES	NO	If No, Resolution Step Completed and repeat step
Does the product order match the unit? - Irradiated, CMV Negative (or equivalent) - Washed, Fresh or Ultrafresh (or acceptable) - Antigen negative, if appropriate - Correct product type (red cell, plasma, platelet or cryo)			

6) Document these Product Dispense Checks below and ensure all steps outlined in the Dispense and Return SOP are followed to dispense the product in CERNER.

	YES	NO	If No, Resolution Step Completed and repeat step
Patient Name and MRN match			
Transfusion Tag is Attached			
DIN and ABORH on Transfusion Tag matches Bag			
Type Differ Sticker is applied when applicable			
Product Code on Transfusion Tag matches the Bag			

7) Confirm Dispense Packing Slip matches Product when placing in Dispense Transport Bag

I have reviewed and confirmed all patient and donor unit information matches original product order and deliver blood product request. All transfusion requirements have been met prior to release of this product.

BB Team Member Initials_____ Date: _____