Department of LABORATORY MEDICINE
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PURPOSE

Provide instructions for ordering, selecting, thawing and allocation of plasma and cryoprecipitate components for transfusion. Includes use of the QuickThaw plasma thawing system and modification of components in the Laboratory Information System (LIS) or on the Downtime Component Prep Log when LIS is unavailable

LOCATION

Northwest Transfusion Support Service (TSS) Montlake Transfusion Service Laboratory (TSL)

PRINCIPLE & CLINICAL SIGNIFICANCE

Principle

Plasma is prepared from whole blood or apheresis collection and frozen at -18°C or colder within 24 hours of collection. On average, each container contains 200 to 250 mL of plasma when prepared from whole blood and as much as 400 to 600 mL when apheresis derived. Plasma is a source of proteins including albumin, fibrinogen, ADAMTS13 and clotting factors I, VII, IX, X and XI. Levels of labile coagulation factor (Factors V and VIII) and stable factors are well above 50% of immediate post-thaw levels in Thawed Plasma stored for up to 5 days. Thawed Plasma contains reduced concentrations of Factor V, VII, and VIII and is not suitable for single-factor replacement when factor concentrates are available

Cryoprecipitate is a crude concentrate of hemostatic proteins prepared from whole blood donation. Cryoprecipitate contains fibrinogen, factor VIII, von Willebrand factor, fibrinogen and factor XIII. Cryoprecipitate is manufactured as single and pooled containers. Pooled cryoprecipitate typically contains 5 single units.

Both plasma and cryoprecipitate components are stored frozen to help maintain factor activity and provide an extended shelf life. Frozen components are thawed at 30-37°C in an FDA approved plasma thawer prior to issue. The thawer gently agitates the component to transfer direct heat into the core of the component for a preset time. At the end of the thawing cycle, agitating stops and the basket will lift and open to retrieve the component. Audio and visual signals indicate when the cycle is complete to prevent leaving the component in the warm bath for an extended amount of time.

Once thawed, plasma is acceptable for transfusion up to 5 days after thawing when stored at 1°C to 6°C. Thawed cryoprecipitate expires 6 hours after thawing and must be stored at 20°C to 24°C.

Clinical Significance

Prophylactic and therapeutic plasma transfusions are commonly indicated to replace missing coagulation factors on patients with an elevated INR before an interventional procedure or during bleeding, respectively. Plasma can be used alone or in combination with albumin as replacement fluid during therapeutic apheresis procedures.

Plasma is indicated in the following conditions:

- Management of preoperative or bleeding patients who require replacement of multiple plasma coagulation factors (e.g. liver disease or DIC)
- Patients undergoing massive transfusion who have clinically significant coagulation deficiencies (i.e. high INR and /or low fibrinogen levels)
- Patients taking warfarin who are bleeding or need to undergo an invasive procedure and prothrombin complex concentrate is not available or is contraindicated
- Transfusion or plasma exchange in patients with thrombotic thrombocytopenic purpura (TTP)
- Management of patients with selected coagulation deficiencies, congenital or acquired or C1 inhibitor, for which no specific coagulation concentrates are available

Cryoprecipitate transfusions are usually indicated for patients with low fibrinogen levels as observed on patients with liver disease, disseminated intravascular coagulation, massive bleeding, and obstetric bleeding. Typically, 2 pooled containers provide enough fibrinogen to raise the fibrinogen level 60-70 mg/dl in an adult

POLICIES

- The following instructions provide the steps for order receipt, thawing, relabeling, and allocation of plasma component for transfusion.
- FDA requires documentation of blood component modifications including date and time of processing and person(s) performing each step. Depending on the process performed, the component type/code, volume, division and/or expiration date/time may be modified.
 - Modifications are documented in the laboratory information system (LIS) and the component relabeled to reflect the modifications prior to issue.
 - In the event, the LIS is unavailable the modifications are documented on a Component Prep Downtime Log at the time concurrent with the modification and later entered in the LIS once recovered.

Component	Storage Requirements		
Frozen Plasma & Cryoprecipitate	≤-18°C		
Thawed Plasma	1°C to 6°C		
Thawed Cryoprecipitate	20°C to 24°C without agitation		

Component Storage Requirements

Plasma Policies

- Pre-transfusion test requirements
 - A historical or current ABO/Rh performed by Montlake TSL is required to issue ABO compatible plasma with the recipient's ABO other than group AB plasma
- Fresh frozen plasma, plasma frozen within 24 hours and apheresis plasma are used interchangeably and relabeled as Thawed Plasma expiring 5 days from the time of thaw
 - Jumbo plasma comes in volumes of 400-600 mL and may be provided for therapeutic plasma exchange procedures. Each jumbo plasma is equivalent to 2 standard plasma (<400 mL) components.
- Select and issue any available compatible thawed plasma before thawing additional components
- Physical modification of blood components is performed prior to documentation of the process in Sunquest or on the Downtime Component Prep Log
- Plasma for plasma exchange orders will be thawed at Montlake TSL and shipped to NW TSS for the scheduled date and time of the procedure.
- Plasma Compatibility:
 - ABO compatible plasma is always provided
 - **ABO identical** plasma is provided when inventory levels, testing and clinical status allow (see Universal Donor Plasma below)
 - **Rh type** is not a consideration in the selection of plasma

Plasma Compatibility Table						
Desistant Taxa		Plasma ABO				
Recipient Type	0	A	В	AB		
0	~	✓	✓	✓		
Α		✓		✓		
В			✓	✓		
AB				✓		
unknown ABO, NTD, or patient <4 months of age				¥		
✓ = compatibility be	etween patient A	ABO and plasma	ABO			

- Universal Donor Plasma (Group AB plasma) is issued in the following circumstances:
 - o No ABO/Rh from Montlake Transfusion Service Laboratory (TSL) on file
 - During a bleeding emergency, Massive Transfusion Protocol, or OB bleed when issue of ABO identical will cause delay
 - Patient is a neonate/infant (< 4 months old). Approval from a UWMC BB MD is required to issue ABO groups other than AB plasma.
 - Intrauterine Transfusions

Cryoprecipitate Policies

• Pre-transfusion test requirements

- Adults: No testing is required
 - Neonate/Infant <4 months of age: No testing to provide group AB cryoprecipitate. ABO typing required to provide ABO identical cryoprecipitate
- Cryoprecipitate Compatibility

Cryoprecipitate Compatibility Table					
Recipient	Then				
Adult	Any ABO/Rh type may be provided				
Neonate/Infant < 4months of age	 Group AB cryoprecipitate should be provided If ABO typing is available, ABO identical cryoprecipitate can be provided Rh type is not a consideration 				

• Frozen pooled cryoprecipitate is relabeled Thawed Pooled Cryoprecipitate and expires 6 hours from the start of the thaw process

SPECIMEN REQUIREMENTS

NA

REAGENTS/SUPPLIES/EQUIPMENT:

Reagents	Supplies	Equipment	
	Helmer plasma overwrap	BB LIS	
	bag	Bar-code scanner	
NA		Helmer Quick Thaw	
		Plasma Thawer	
		NIST Thermometer	

QUALITY CONTROL:

- Plasma thawer water temperatures are checked and recorded daily
- Components are placed into plasma overwrap bags before placing in the thawer basket to protect the plasma bag from water-borne contaminants and the water bath from contaminants if the component bag breaks

INSTRUCTIONS

 TABLE of CONTENTS:

 Order Receipt

 Thawing Components

 Blood Component Preparation (LIS)

 Blood Label Check (LIS)

 Allocating Component to Patient

 Blood Label Reprint

Order Receipt

STEP	ACTION					
	Receive product orde	er requisitio	n			
	If order is placed Then Then					
1	In Soarian	Requisition and Montla	n will print at NW TSS ake TSL	Montlake TSL will place the		
	On manual	NW TSS f	axes a copy of	order in the LIS		
2						
2						
3	Click on Sunquest, E	lood Bank	Inquiry (BBI			
4	Select <u>L</u> ookup by 'Pa	atientID' and	d enter the patient me	dical record number (MRN)		
	 Review the patient historical record for the following: Patient's ABO /Rh –test result must be from Montlake TSL Any restrictions or special requirements Age: Neonate/Infant < 4 months old Some patients may receive plasma components only after UWMC Blood Bank (TSL) MD approval due to their clinical status (i.e. IgA deficiency, acuters transfusion manufacture) 					
5	lf		Then			
	Any discrepancies between order and patient historical requirements found OR TSL MD approval is required		 Contact Montlake TSL for resolution Go to next step when discrepancy is resolved 			
	No discrepancies for	ound	Go to next step			
	If order for		Then			
6	Plasma		Go to next step			
	Cryoprecipitate		Go to step 9			
	Verify patient has an	ABO/Rh pe	erformed by Montlake	TSL		
	If patient has		Then			
	Valid ABO		Go to next step			
7	No ABO performed by Montlake TSL		Notify the clinical team to order ABO/Rh test or Type and Screen NOTE: Both are recommended if the patient is bleeding and likely to need additional blood			
			If priority is	Then		
			Routine	Go to next step when the ABO/Rh is complete		

STEP	ACTION				
		STAT Communicate testing TAT and product availability to ordering provider to determine if order needs to be changed to emergency.			
		Emergency/MTP/•Select Group AB plasmaOB Bleed•Go to Step 8			
8	Select plasma according to the Plasma Compatibility Table in the following order 1 st option: ABO identical 2 nd option: ABO compatible 3 rd option: Group AB NOTE: To look for available inventory in Sunquest: Click on Sunquest, Blood Inv/Supplier Search and enter the following: Field Enter HID U Component Type PLSG Unit Location NWBB Search Mode Default: Available, Allocated, Unprocessed Click <search></search>				
9	Select appropriate pooled cryoprecipitate – refer to <u>Cryoprecipitate Compatibility Table</u> above				
	If component is	Then			
10	Thawed	Go to section Allocating Component to Patient			
	Frozen	Go to section Thawing Components			

Thawing Components

STEP	ACTION
1	 Remove the frozen component from protective packaging and verify the following: Unit is not expired Ports are intact Container has no visible cracks or leaks No evidence of previous thaw (i.e. plasma is frozen with a visible bubble in the back center – shifting of the bubble location or unexpected denting may be an indication of thawing and refreezing NOTE: Do not discard the protective packaging. Packaging should be returned to Montlake TSL for return to the blood supplier.

STEP	ACTION						
	If co	mponent is	Then				
	Acce	ptable	Go to next step				
2	Unac	 Select a replacement component Physically quarantine the unacceptable component and initiate a QI form – refer to SOP <i>Returning Blood</i> <i>Components to Montlake from Northwest Campus</i> 					
2	Place	the frozen compo	nent into an over	wrap plastic bag			
3	NOTE	: Components is	placed in an over	wrap bag to prevent contamination			
4	Push t	he LIFT OUT but	ton to rais	e and open the basket(s)			
5	Hang	the product in the	overwrap bag on	the tabs at the top of the basket			
	Docun	nent the time the	components were	e placed in the thawer on the requis	sition		
6	NOTE electro	: This time will be onic thaw process	the time of proce in the Blood Con	essing entered in the LIS when perf nponent Preparation Module	orming the		
7	Set the until th autom	e thaw time based ne correct time is atically)	d on the table belo shown. ('HO" mea	ow by pressing the CYCLE TIME b ans "hold" and the thawing cycle wi	utton II not end		
	Component		onent	Median Thaw Time (minutes)			
	Plasma			16			
		Cryoprecipitate		8			
8	Press	the CYCLE STAF	RT button t	to lower the basket and start the th	aw cycle		
	lf		Then				
9	 Cycle needs to be paused or stopped Press the LIFT OUT button to raise the basket temporarily. Press LIFT OUT again to resume the thaw cycle 						
10	Unload component(s) from the basket when the cycle is complete or stopped						
	Remove the product from the overwrap bag and visually inspect the component (refer to						
		Visual Inspection	<u>1 of Blood Comp</u> Then	oonents at Northwest Campus			
	Acce	ptable	Go to next step				
11	Unac	ceptable	• Physically quarantine the component • Initiate a QI form • Return the component with the QI form to Montlake TSL according to SOP: <i>Quarantine and Final Disposition of</i>				

STEP		ACTION
		Blood Components at Northwest Campus
	Leaking or broken container	 Discard the component according to SOP <i>Quarantine</i> and <i>Final Disposition of Blood Components at</i> <i>Northwest Campus</i> Notify Montlake TSL and fax a copy of the QI form Place QI form in NW Transfusion Medicine Supervisor's Mailbox
	Component is not completely thawed	Return to step 5 and thaw in 3 MINUTE increments until completely thawed
12	Go to section Blood C	omponent Preparation to modify the component to thawed in

Blood Component Preparation (LIS)

STEP	ACTION					
1	Click on Sunguest, Blood Component Preparation (BCP)					
	Enter component prep code in the 'Value Field' and press the <tab> key</tab>					
	Enter code E	Example				
2	T + E code TI	TE1624				
	Enter the Date in the 'Date	t <u>e</u> field'				
	If component was placed in thawer	Then				
2	Today	Press the <tab></tab>	key to default today's date			
3	Yesterday NOTE: This may occur when thawing starts before midnight	Enter yesterday's date				
	Enter the time the compo	nent was loaded ir	the thawer in the 'Time' filed			
4	NOTE: This is the time do	ocumented in <u>step</u>	6, section Thawing Components			
5	Select the current work s	hift using the 'Shi <u>f</u> t	field' dropdown arrow			

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STEP	ACTION						
	If additional	techs	Then				
6	Did not participated in the thaw process		Go to next s	Go to next step			
	Participated i process	n the thaw	Enter the 4- code' Click the <a< td=""><td>digit tech code of part dd> button</td><td>icipants in the <u>'T</u>ech</td></a<>	digit tech code of part dd> button	icipants in the <u>'T</u> ech		
7	Click the < <u>C</u> or	ntinue> butto	on at the botto	om right of screen			
	Scan the follo	wing barcod	es in the asso	ociated field			
	Field	Barcode					
	<u>U</u> nit #	Donor Ide	ntification Nur	nber	W1416 20 211696 8 2		
8	C <u>o</u> mponent	Product Ecode IMPORTANT : Although the component code may prefill after scanning the unit #, scanning of the component code is required to ensure the correct component is selected			E1624V00 APHERESIS PLASMA FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY		
	Division	This field s ecode is s manually i and the di NOTE: Th	s field should auto populate when the ode is scanned, when applicable. Enter nually if processing a divided product the division does not auto populate				
		divisions (AO,BO,CO,D	O) of a unit	Store at 1 to 6 C Part B0		
	Respond to ar	ny message:	s that appear	such as the following	:		
	Message			Then			
	Blood Component F	Prep	×	Review the input an both are correct	d process codes to verify		
	Component T Continue?	ype does not match mair	tenance definitions.	If information is	Then		
0			K Cancel	Incorrect	Click <cancel> and</cancel>		
				Component type is not found SQ and needs to be added	 Click <cancel></cancel> Call UW TSL & ask for Lead MLS for resolution Complete a QI 		
					form and fax copy to Montlake TSL		

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STEP	ACTION					
						Place QI form in NW Transfusion Medicine Supervisor's Mailbox
	Blood Component Prep Image: A start of the following unit(s) requires a product code. Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print for the following unit(s): Without a product code on file, no label will print f			 Click <ok></ok> Click on SunQuest, BB Label Print Click on SunQuest, BB Label Print to reprint the label and perform the Blood Label Check following modification of the component Click 'OK' This is a reminder to perform the blood label check following the product modification 		
	Actionalinding international Company	there and pressage takes authority to even type are not optimized and a type and type are not optimized and type are		outpu than t accor limits	t expiration dat the input expiration dat dance with the listed below in	te/time to be no later ation date/time and in processing expiration step 8.
10	Fill in all yello	w highlighted fields	s that are	blanl	< in the 'Unit Da	ata' section prior
	Verify the exp	piration date and tir	ne are ac	ccurat	e even if auto f	filled by the system
	Process	Component	Type	1	Expiration Da	ate/time Limits
11	Thawing	Plasma	Closed		5 days from thawing	
••	Thawing	Cryoprecipitate	Closed	d 6 hours from thawing		thawing
	NOTE: Expiration or modified c	ation dates/times <u>M</u> omponent	<u>IUST ALI</u>	WAY:	<u>S</u> be the shorte	est outdate of the original
12	Click <save></save>	when all entries a	re entered	d and	verified	
13	Click <finish: ISBT label wi</finish: 	> when the preview Il print	v output/n	new u	nits box appea	r and the new component
14	Retrieve the NOTE: If no I	new label from the abel printed, go to	label prin section <u>B</u>	nter Blood	Label Reprint t	o reprint labels
15	Verify all info	rmation on the labe	el is accur	rate	· · ·	
	Place the new	w label on the comp	conent ov	ver the	e top of the orio	ginal
16	NOTE: The c removed or c	original donor identi overed over with a	fication n new labe	iumbe el	er on the contai	ner should never be

STEP	ACTION
17	Draw one line through the supplier license #
18	Go to section Blood Label Check

Blood Label Check (LIS)

STEP	ACTION			
1	Click on Sunquest Blood Label Check			
	Scan the following barcodes in the associated field			
	Field	Barcode		
2	<u>U</u> nit #	Donor Identification Number	W1416 20 211696 8 2	
	C <u>o</u> mponent	Product Ecode IMPORTANT : Although the component code may prefill after scanning the unit #, scanning of the component code is required to ensure the correct component is selected	E2284VB0 THAWED APHERESIS PLASMA Divided FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY	
	Division	This field should auto populate when the ecode is scanned, when applicable. Enter manually if processing a divided product and the division does not auto populate NOTE: The same donation (unit #) may be split into multiple containers or parts (AO,BO,CO,DO)	E2284VB0 THAWED APHERESIS PLASMA Divided FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY 219 mL containing approx 33mL ACD - A Store at 1 to 6 C Part B0	

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STEP	ACTION		
3	Click <search> NOTE: Unit information will populate the middle section of the screen. Mandatory fields will be highlighted in yellow.</search>		
4	Click in the ' <u>A</u> BO on Label' field and scan the ABO/Rh barcode on the unit label NOTE: Both the ABO and Rh fields will populate		
5	Click in the 'Expiration <u>D</u> ate' field and scan the expiration date/time barcode from the unit label NOTE: Both the Date and Time will populate		
	Click <check label=""></check>	Then	
	Label is correct	 The screen will refresh to a new Blood Label Check screen with unit #, component and division # retained Go to the next step 	
6	A discrepancy occurred during the check. EXAMPLE: Blood Label Check ABO/Rh on label does not match ABO/Rh in permanent file. Expiration date/time on label does not match expiration date/time in unit permanent file.	 A warning will appear explaining the discrepancy and the label will not be checked. Click OK, resolve the discrepancy and repeat steps 3-6 verifying all information. Do not issue the component 	
7	Go to section Allocating Component to Patient	until the label change correct	

Allocating Component to Patient

STEP	ACTION		
1	Contact a Montlake MLS to allocate the component to the recipient in Sunquest		
2	 Read the following information to the Montlake MLS request they perform a verbal read back Patient Medical Record Number Full Patient Name as it appears on the order Type of component Unit number of the component Montlake MLS will perform a verbal read back by the of all 4 items – verify information is correct 		
3	 Montlake TSL logs into SQ location: NWBB2 to allocate the thawed plasma components The Transfusion Record will print at NW TSS when allocation is complete 		

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STEP	ACTION		
Δ	Retrieve the Transfusion	Record from printer	
4	NOTE: Printing occurs immediately after allocation		
5	Attached the Transfusion Record and Unit Compatibility Label to the component following SOP Attaching Sunguest Transfusion Record to Blood Components at		
•	Northwest Campus		
	If product	Then	
6	Ready to issue	Issue following SOP Issuing Blood Components at Northwest Campus	
	Will issue a later time	Place in backup blood refrigerator	

Blood Label Reprint (only perform if label does not print at the end of Blood Component Prep):

STEP	ACTION			
1	Click on Sunquest,	BB Label Print		
2	Select the 'Product/Date' option from the <u>L</u> abel type dropdown box at the top left of the screen		Blood Bank Label Print Session Label type Product/Date Num. of copies 1 Unit Selection Unit # Clear Omponent Division # Clear	
	Scan the following Field	barcodes in the associated field Barcode	1	
3	<u>U</u> nit #	Donor Identification Number	Imber W1416 20 211696 8 2	
	C <u>o</u> mponent	Product Ecode IMPORTANT : Although the component code may prefill af scanning the unit #, scanning of the component code is require to ensure the correct component is selected	ter E2284VB0 of THAWED APHERESIS PLASMA Divided FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY	
	Division	When applicable, the field will automatically populate when the ecode is scanned. Enter manually if not. NOTE: The same donation (unit #) may be split into multiple containers (AO,BO,CO,DO) or parts		

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STEP	ACTION		
4	Click <add></add>		
5	Repeat steps 3-6 if additional labels of the same type need to be printed.		
6	Click <print> when all units are entered to print the labels</print>		
7	Click <exit> to close Blood Bank Label Print</exit>		

CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL VALUES/CRITICAL VALUES

NA

PROCEDURE NOTES AND LIMITATIONS:

- A label check must be performed and entered in Sunquest after any modification. Sunquest
 programming does not have a mandatory setting for performing this check, but a label check
 <u>MUST</u> be performed.
- Any deviation from this procedure should be approved by the Montlake TSL MD-On -Call and the deviation documented on a QI form (include the name of the MD approving the deviation)
- Use only tap or distilled water to fill the thaw bath. Do not use deionized water as it may be corrosive to the chamber and baskets

REFERENCES:

- Standards for Blood Banks and Transfusion Services, American Association of Blood Banks, Bethesda, MD. Current Edition.
- Sunquest Blood Bank Users' Guide Version 8.1

RELATED DOCUMENTS:

FORM Component Prep Downtime Log SOP Returning Blood Components to Montlake from Northwest Campus SOP Visual Inspection of Blood Components at Northwest Campus SOP Quarantine and Final Disposition of Blood Components at Northwest Campus SOP Attaching Sunquest Transfusion Record to Blood Components at Northwest Campus SOP Issuing Blood Components at Northwest Campus

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UWMC SOP Appro	oval:			
UWMC CLIA Medical Director	marlien	Data	06/20/20	
	Mark H. Wener, MD	Date		
Transfusion Service Manager	Mina Sen	Date	10/16/20	
QARA Manager	Christine Clark	Date	10-16-2021	
Transfusion Service Medical Director	Monica B. Pagano, MD	Date	10-19-2020	
UWMC Biennial Review:				
	T	Date		
		Date		