University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA 98195 Transfusion Services Laboratory Policies and Procedures Manual Original Effective Date: 10-28-2020

Number: PC-0085.02

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TITLE: Ordering and Processing Plasma and Cryoprecipitate at Northwest Campus

### **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.

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# **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** 

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

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## **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.</li>
- 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:
  - o ABO compatible plasma is always provided
  - ABO identical plasma is provided when inventory levels, testing and clinical status allow (see Universal Donor Plasma below)
  - o **Rh type** is not a consideration in the selection of plasma

	Plasma Compatibility Table				
B	Plasma ABO				
Recipient Type	0	Α	В	AB	
0	✓	✓	✓	✓	
Α		<b>✓</b>		✓	
В			✓	✓	
AB	<b>Y</b> 7			✓	
unknown ABO, NTD, or patient <4 months of age				<b>✓</b>	

√ = compatibility between patient ABO and plasma ABO

- Universal Donor Plasma (Group AB plasma) is issued in the following circumstances:
  - 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

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# **Cryoprecipitate Policies**

- Pre-transfusion test requirements
  - o Adults: No testing is required
  - Neonate/Infant <4 months of age: No testing to provide group AB cryoprecipitate.</li>
     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	<ul> <li>Group AB cryoprecipitate should be provided</li> <li>If ABO typing is available, ABO identical cryoprecipitate can be provided</li> <li>Rh type is not a consideration</li> </ul>			

 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
	<ul> <li>Helmer plasma overwrap</li> </ul>	BB LIS
	bag	<ul> <li>Bar-code scanner</li> </ul>
NA		<ul> <li>Helmer Quick Thaw</li> </ul>
		Plasma Thawer
		<ul> <li>NIST Thermometer</li> </ul>

### **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** 

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**Order Receipt** 

Order R	eceipt					
STEP	ACTION					
	Receive product order requisition					
	If order is placed	Then		Then		
1	In EPIC Requisition will print at NW 1 and Montlake TSL		ake TSL	Montlake TSL will receive/place the order in		
	On manual requisition		axes a copy of to Montlake TSL	the LIS		
2	Log into SQ using La	ab Location:	NW			
3	Click on Sunquest, E	Blood Bank	Inquiry (BBI			
	Select <u>L</u> ookup by	/ 'PatientID'	and enter the patient m	edical record number (MRN)		
	<ul> <li>Select the MRN a</li> <li>Blood Bank Inquiry</li> </ul>	associated v	with HID: U			
	er blood bank Inquiry					
	Lookup by Patient ID	~	<u>V</u> alue <u>U9033933</u>	Search		
4			By Default HID Only			
	Search found 2 patients	matching "Dati	ent ID-110033033"			
	Name Patie			Sex Status Alt/OS Pa		
	TSTMRT,OR U9033 TSTMRT,OR U9033		06/21/1980 06/21/1980	M ACT M PRE		
	Review the patient historical record for the following:					
			ılt must be from Montlak	ke TSL		
	<ul> <li>Any restrictions of Age: Neo</li> </ul>		quirements < 4 months old			
	•			ents only after UWMC Blood		
				status (i.e. IgA deficiency,		
5	If	ansfusion re	Then			
	Any discrepancies I	netween	IIICII			
	order and patient hi	storical	Contact Montlake	TSI for resolution		
	requirements found OR			en discrepancy is resolved		
	TSL MD approval is	required	•	. ,		
	No discrepancies found Go to next step					
	If order for		Then			
6	6 Plasma Go to next step					
	Cryoprecipitate		Go to step 9			
	Verify patient has an ABO/Rh performed by Montlake TSL					
7						
	If patient has		Then			

STEP	ACTION					
	Valid ABO		Go	to next step		
			NO ble	oe and Screen  TE: Both are reco	ommended if the patient is need additional blood	
				priority is	Then	
	No ABO perf Montlake TS		R	Routine	Go to next step when the ABO/Rh is complete	
			S	STAT	Communicate testing TAT and product availability to ordering provider to determine if order needs to be changed to emergency.	
			С	mergency/MTP/ B Bleed	<ul><li>Select Group AB plasma</li><li>Go to Step 8</li></ul>	
	Select plasma according to the Plasma Compatibility Table in the following order  1st option: ABO identical 2nd option: ABO compatible 3rd option: Group AB  NOTE: To look for available inventory in Sunquest:  Click on Sunquest, Blood Inv/Supplier Search and enter the					
8		owing:		<u> </u>		
		Field	7	Enter		
		Component Type		PLSG		
		Component Type Unit Location		NWBB		
	Search Mode			Default: Available, Allocated, Unprocessed		
		ck <search></search>			· · ·	
9	Select approp above	riate pooled cryop	recip	oitate– refer to <u>Cry</u>	oprecipitate Compatibility Table	
	If component is		Т	Then		
10	Thawed		G	Go to section Allocating Component to Patient		
	Frozen		G	Go to section Thawing Components		

# **Thawing Components**

STEP			ACTION	
1	<ul> <li>Remove the frozen component from protective packaging and verify the following: <ul> <li>Unit is not expired</li> <li>Ports are intact</li> <li>Container has no visible cracks or leaks</li> <li>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</li> </ul> </li> <li>NOTE: Do not discard the protective packaging. Packaging should be returned to Montlake TSL for return to the blood supplier.</li> </ul>			
	If component is	Then		
	Acceptable	Go to next step	,	
2	Unacceptable	Physically of initiate a QI	placement component quarantine the unacceptable compor form – refer to SOP <b>Quarantine ar</b> In of <b>Blood Component</b> .	
	Place the frozen compo	nent into an ove	rwrap plastic bag	
3	NOTE: Components is a	olaced in an ove	rwrap bag to prevent contamination	
4	Push the LIFT OUT button to raise and open the basket(s)			
5	Hang the product in the overwrap bag on the tabs at the top of the basket			
			e placed in the thawer on the requis	ition
6	NOTE: This time will be the time of processing entered in the LIS when performing the electronic thaw process in the Blood Component Preparation Module			
7	Set the thaw time based on the table below by pressing the CYCLE TIME button until the correct time is shown. ('HO" means "hold" and the thawing cycle will not end automatically)  Component Median Thaw Time (minutes)			
	Plasma		16	
	Cryoprecipitate 8			
8	Press the CYCLE STAR	et button	to lower the basket and start the that	aw cycle
	If	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			
	1 1 1000 En 1 001 again to 100 and the that by sid			

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STEP	ACTION				
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 SOP <i>Visual Inspection of Blood Components at Northwest Campus</i>				
	If component is	Then			
	Acceptable	Go to next step			
11	Unacceptable	<ul> <li>Physically quarantine the component</li> <li>Initiate a QI form</li> <li>Return the component with the QI form to Montlake TSL according to SOP: Quarantine and Final Disposition of Blood Components at Northwest Campus</li> </ul>			
	Leaking or broken container	<ul> <li>Discard the component according to SOP Quarantine and Final Disposition of Blood Components at Northwest Campus</li> <li>Notify Montlake TSL and fax a copy of the QI form</li> <li>Place QI form in NW Transfusion Medicine Supervisor's Mailbox</li> </ul>			
	Component is not completely thawed	Return to step 5 and thaw in 3 MINUTE increments until completely thawed			
12	Go to section Blood C Sunquest	omponent Preparation to modify the component to thawed in			

**Blood Component Preparation (LIS)** 

STEP	ACTION		
1	Click on Sunquest, Blood Component Preparation (BCP)		
	Enter component prep code in the 'Value Field' and press the <tab> key</tab>		
	Enter code E	Example	
2		TE1624	APHERESIS PLASMA FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY
	NOTE: The Ecode is found on the front of the component label  Enter the Date in the 'Date field'		
		<u> </u>	
3	If component was placed in thawer	Then	
	Today	Press the <tab> ke</tab>	ey to default today's date

STEP	ACTION			
	NOTE: This when thawing before midnig	g starts	Enter yesterday's date	
4	Enter the time the component was loaded in the thawer in the 'Time' filed <b>NOTE:</b> This is the time documented in <u>step 6, section Thawing Components</u>			
5	Select the cur	rent work sh	nift using the 'Shi <u>f</u> t field' dropdown a	arrow
	If additional	techs	Then	
6	Did not partic	•	Go to next step	
	Participated i process	in the thaw	Enter the 4-digit tech code of part code' Click the <add> button</add>	icipants in the ' <u>T</u> ech
7	Click the < Cor	ntinue> butte	on at the bottom right of screen	
	Field  Unit #	Barcode	ntification Number	W1416 20 211696 8 2
8	C <u>o</u> mponent	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  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 unit# may have multiple divisions (AO,BO,CO,DO) of a unit    IMPORTANT: Although the component code is #1624V00   APHERESIS   PLASMA   PROZEN WITHIN 24 HOURS   AFTER PHLEBOTOMY   E2284VB0   THAWED APHERESIS   PLASMA   DIVIDED   FROZEN WITHIN 24 HOURS   AFTER PHLEBOTOMY   219 mL containing approx 3 mL   ACD - A   Store at 1 to 6 C   Part 80   Part 80		
	Division			
	Respond to any messages that appear such as the following:			
9	Message	e Then		

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STEP		ACTION	
	Blood Component Prep	Review the input an both are correct	d process codes to verify
	Component Type does not match maintenance definitions. Continue?	If information is	Then
		Incorrect  Component type is not found SQ and needs to be added  • Click <ok></ok>	Then  Click <cancel> and correct the error  Click <cancel> Call UW TSL &amp; ask for Lead MLS for resolution  Complete a QI form and fax copy to Montlake TSL  Place QI form in NW Transfusion Medicine Supervisor's Mailbox  est, BB Label Print</cancel></cancel>
	Without a product code on file, no label will print for the following unit(s):  W141681000130 AUTRI2:00	to repri the Blood Label modification of t	9
	Blood Component Prep  Unable to add testing battery BLC to the output unit. Previous testing battery already associated to unit.	<ul><li>Click 'OK'</li><li>This is a remind</li></ul>	er to perform the blood wing the product
	S QA warnings Found  QA sarnings found, controls  Acknowledge Shat Come Type y  W141651000300 82379 00 Prod and equ. date (CO/4/2/318 2339) prior  W141651000300 82379 00 to Color dep. date (CO/4/2/318 2339) prior  To Color dep. date (CO/4/2/318 2339) prior  To Color dep. date (CO/4/2/318 2339) to Color dep	output expiration da than the input expira	arning and update the te/time to be no later ation date/time and in processing expiration step 8.
10	Fill in all yellow highlighted fields that ar	e blank in the 'Unit D	ata' section prior

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STEP	ACTION				
	Verify the expiration date and time are accurate even if auto filled by the system				
	Process	Component	System Type	Expiration Date/t	ime Limits
44	Thawing	Plasma	Closed	5 days from thawi	ng
11	Thawing	Cryoprecipitate	Closed	6 hours from thaw	ring
	NOTE: Expire or modified c		IUST <u>ALWAY</u>	<b>S</b> be the shortest o	utdate of the original
12	Click <save></save>	when all entries ar	re entered and	verified	
13	Click <finish> when the preview output/new units box appear and the new component ISBT label will print</finish>				
14	Retrieve the new label from the label printer  NOTE: If no label printed, go to section Blood Label Reprint to reprint labels				
15	Verify all information on the label is accurate				
	Place the new label on the component over the top of the original				
16	<b>NOTE:</b> The original donor identification number on the container should never be removed or covered over with a new label				should never be
17	Draw one line	e through the suppl	ier license #		W1416 20 671053 SV  Bloodworks Seattle, WA 98104  FDA Registration Number 3071347 US License Number 3071347 US License Number 30242  Apoptly Identify Intended Recipient Sea circular of Information for Indications, Total Control of Control of Control of Control This product may transmit infectious agents.  R2 Only  VOLUNTEER DONOR  THAWED PLASMA
18	Go to section	Blood Label Chec	<u>k</u>		

Blood Label Check (LIS)

STEP		ACTION
1	Click on Sunque	est Blood Label Check
2	Scan the following Field	ng barcodes in the associated field  Barcode

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STEP	ACTION			
	<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 populat  NOTE: The same donation (unit # may be split into multiple containe or parts (AO,BO,CO,DO)	E2284VB0 THAWED APHERESIS PLASMA DIVIDED FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY 219 mL containing approx 33mL	
3	Click <search>  NOTE: Unit information will populate the middle section of the screen. Mandatory fields will be highlighted in yellow.</search>			
4	will be highlighted in yellow.  Click in the 'ABO 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>Date</u> ' field and scan the expiration date/time barcode from the unit label  NOTE: Both the Date and Time will populate			
	Click <check label=""></check>			
6	Label is correct	rt	Then  The screen will refresh to a new Blood Label Check screen with unit #, component and division # retained  Go to the next step	
	A discrepancy EXAMPLE:	occurred during the check.	<ul> <li>A warning will appear explaining the discrepancy and the label will not be checked.</li> <li>Click OK, resolve the</li> </ul>	

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STEP	ACTION	
	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.  OK	discrepancy and repeat steps 3-6 verifying all information.  • Do not issue the component until the label change correct
7	Go to section Allocating Component to Patient	

**Allocating Component to Patient** 

STEP	ACTION		
1	Contact a Montlake MLS to allocate the component to the recipient in Sunquest		
2	<ul> <li>Read the following information to the Montlake MLS request they perform a verbal read back         <ul> <li>Patient Medical Record Number</li> <li>Full Patient Name as it appears on the order</li> <li>Type of component</li> <li>Unit number of the component</li> </ul> </li> <li>Montlake MLS will perform a verbal read back by the of all 4 items – verify information is correct</li> <li>Montlake TSL logs into SQ location: NWBB2 to allocate the thawed plasma components</li> </ul>		
4	The Transfusion Record will print at NW TSS when allocation is complete  Retrieve the Transfusion Record from printer  NOTE: Printing occurs immediately after allocation		
5	Attached the Transfusion Record and Unit Compatibility Label to the component following SOP Attaching Sunquest Transfusion Record to Blood Components at Northwest Campus		
6	Ready to issue  Will issue a later time	Then Issue following SOP Issuing Blood Components at Northwest Campus 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

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STEP	ACTION			
2	Select the 'Product/Date' option from the Label 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 # Component Division #  Add	
	Scan the followin	g barcodes in the associated fie	eld	
	Field	Barcode		
	<u>U</u> nit #	Donor Identification Number	W1416 20 211696 8 2	
3	C <u>o</u> mponent	Product Ecode  IMPORTANT: Although the component code may prefill scanning the unit #, scanning the component code is requi to ensure the correct composis selected	g of PLASMA DIVIDED	
	Division	When applicable, the field will automatically populate whe code is scanned. Enter manually if not.  NOTE: The same donation (unit #) may be split into multicontainers (AO,BO,CO,DO) or parts		
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
MUST be performed.

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- 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 Sunguest Transfusion Record to Blood Components at Northwest Campus

SOP Issuing Blood Components at Northwest Campus

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UWMC SOP Approval:		
UWMC CLIA Medical Director		
	Mark H. Wener, MD	Date
Transfusion Service Manager		Date
_	Nina Sen	
Compliance Analyst		Date
Transfusion	Christine Clark	
Service		
Medical Director		Date
	Monica Pagano, MD	
UWMC Biennial Review:		
		Date
		Date

# **REVISION HISTORY:**

03/01/2021: Updated for conversion from Cerner to Epic eMR on 03/27/2021