University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA 98195 Transfusion Services Laboratory Policies and Procedures Manual	Original Effective Date: 03-11-16 Revision Effective Date: 04-22-18	Number: PC-0001.02
TITLE: **Blood Component Preparation**		

PURPOSE
To provide instruction for documenting processing and modification of components in Sunquest or on the Downtime Component Prep Log when Sunquest is unavailable

PRINCIPLE & CLINICAL SIGNIFICANCE
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 change. These changes must be documented and the component label updated to reflect these changes prior to issue.

POLICIES
- Physical modification of blood components is performed prior to documentation of the process in Sunquest or on the Downtime Component Prep Log
- Do not separate divided products until the label check has been performed
- When multiple processes are applied to the same blood component, document each individual process when completed before performing additional processes
- Supplies used during product modification must be documented in Sunquest or on the Downtime Blood Component Prep Log
- Weld checks made using the sterile tubing welder must be documented in Sunquest or on the Downtime Blood Component Prep Log

SPECIMEN REQUIREMENTS NA

REAGENTS/SUPPLIES/EQUIPMENT:

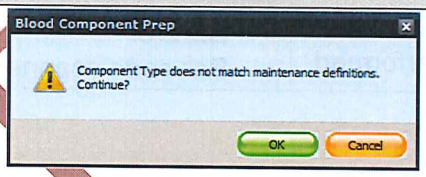
Reagents	Supplies	Equipment
NA	Refer to SOP specific for the modification being performed	• BB LIS • Bar-code scanner

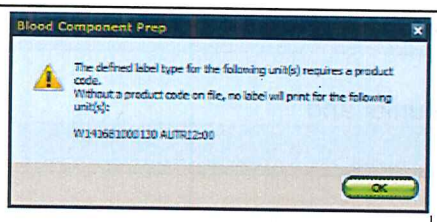
QUALITY CONTROL:
The LIS is validated upon implementation and upgrades.

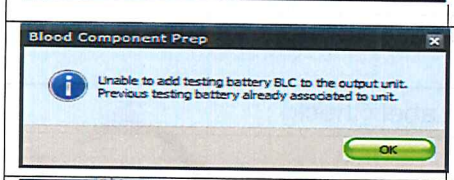
INSTRUCTIONS
TABLE of CONTENTS:

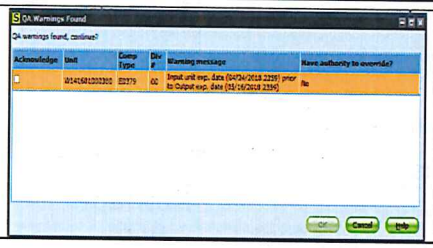
General Component Processing

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>1</td><td>Open Blood Component Preparation (BCP) in Sunquest</td></tr>
<tr><td>2</td><td>Enter component prep code in the “Value Field”
<table>
<tr><th>Process</th><th>Enter code</th><th>Example</th></tr>
<tr><td>Thaw</td><td>T + E code</td><td>TE0869</td></tr>
<tr><td>Irradiation</td><td>I + E code</td><td>IE0336</td></tr>
<tr><td>Wash</td><td>W + E code</td><td>WE0336</td></tr>
<tr><td>Volume Reduce</td><td>V + E code</td><td>VE0336</td></tr>
<tr><td>Combining double bag apheresis platelets</td><td>COMBIN</td><td>COMBIN</td></tr>
<tr><td>Irradiation of Autologous Unit</td><td>IRRAUT</td><td>IRRAUT</td></tr>
<tr><td>Irradiate HLA Platelet, no bag or bag 1</td><td>IRRHLA</td><td>IRRHLA</td></tr>
<tr><td>Irradiate HLA Platelet, bag 2</td><td>IRHLA2</td><td>IRHLA2</td></tr>
<tr><td>Irradiate HLA Platelet, bag 3</td><td>IRHLA3</td><td>IRHLA3</td></tr>
<tr><td>Irradiate HLA PAS Platelet, no bag, or bag 1</td><td>IHPAS</td><td>IHPAS</td></tr>
<tr><td>Irradiate HLA PAS Platelet, bag 2</td><td>IHPAS2</td><td>IHPAS2</td></tr>
</table></td></tr>
<tr><td>3</td><td>TAB through today’s date and time to enter the current time or correct if necessary if entering data from a Downtime Blood Component Prep Log</td></tr>
<tr><td>4</td><td>• Verify the correct shift is entered in the Shift field
• Enter any additional processing tech IDs (if applicable)
• Click <Add>
• Click <Continue></td></tr>
<tr><td>5</td><td>• Scan the Unit # and Component type in the appropriate fields
• Scan the Division # (if applicable)

NOTE: Although the component code may prefill after scanning the unit #, scanning of the component code is required to ensure the correct component is selected</td></tr>
<tr><td>6</td><td>Respond to any messages that appear such as the following
<table>
<tr><th>Message</th><th>Then</th></tr>
<tr><td> 
</td><td>Review the input and process codes to verify both are correct
<table>
<tr><th>If information is</th><th>Then</th></tr>
<tr><td>Incorrect</td><td>Click <Cancel> and correct the error</td></tr>
<tr><td>New input component needs to be added to the LIS</td><td>• Click <Cancel>
• Refer to a MLS Lead for resolution
• Complete a QI document to added component to LIS</td></tr>
</table></td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td> 

Click <OK>
Use Blood Label to reprint the label and perform the Blood Label Check following modification of the component</td></tr>
<tr><td></td><td> 

Click 'OK'
This is a reminder to perform the label check following the product modification</td></tr>
<tr><td></td><td> 

Acknowledge the warning and update the output expiration date/time to be no later than the input expiration date/time and in accordance with the processing expiration limits listed below in step 8.</td></tr>
<tr><td>7</td><td colspan="2">Fill in all yellow highlighted fields that are blank in the 'Unit Data' section prior</td></tr>
<tr><td>8</td><td colspan="2">Verify the expiration date and time are accurate even if auto filled by the system
<table>
<tr><th>Process</th><th>Component</th><th>System Type</th><th>Expiration Date/time Limits</th></tr>
<tr><td>Irradiation</td><td>Platelets</td><td>Closed</td><td>No change</td></tr>
<tr><td>Irradiation</td><td>RBC</td><td>Closed</td><td>Original expiration or 28 days from date of irradiation, whichever is sooner</td></tr>
<tr><td>Washing</td><td>Platelets</td><td>Open</td><td>4 hours from spiking</td></tr>
<tr><td>Washing</td><td>RBC</td><td>Open</td><td>24 hours from spiking</td></tr>
<tr><td>Thawing</td><td>Plasma</td><td>Closed</td><td>5 days from thawing</td></tr>
<tr><td>Thawing</td><td>Prepooled Cryo</td><td>Closed</td><td>6 hours from thawing</td></tr>
<tr><td>Combining</td><td>Platelet Pheresis</td><td>Closed</td><td>24 hours from combining</td></tr>
</table>
NOTE: Expiration dates/times **MUST ALWAYS** be selected by the shortest outdate of the original unit or the modified unit.</td></tr>
<tr><td>9</td><td colspan="2">Click <Save> when all entries are entered and verified</td></tr>
<tr><td>10</td><td colspan="2">Click <Finish> when the preview output/new units box appears</td></tr>
<tr><td>11</td><td colspan="2">Retrieve the ISBT label (full face or ½ face(product /date)
<table>
<tr><th>Modification Process</th><th>Type of Label Printed</th></tr>
<tr><td>Washing</td><td>Full Face</td></tr>
<tr><td>Irradiation</td><td>Half face</td></tr>
<tr><td>Thawing</td><td>Half face</td></tr>
<tr><td>Volume Reducing</td><td>Half face</td></tr>
</table></td></tr>
</table>

	NOTE: If no label printed, go to section Blood Label Reprint to reprint labels
12	• Verify all information is accurate • Place the new labels on the appropriate units and

Label is a	Then
Full face	Go to next step
Half face	• Draw a line through the supplier license # • Go to next step

13	Perform a label check (go to section Blood Label Check)

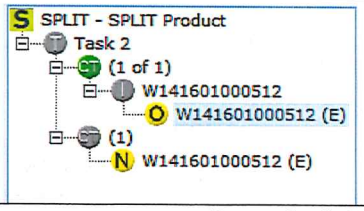
Dividing Products

STEP	ACTION
1	Open Blood Component Preparation (BCP) in Sunquest
2	Enter component prep code in the "Value Field"

Process	Description of change to product	Product type	Enter Code
Aliquot into a syringe	• Original bag retains original expiration date/time. • New product defaults to 4hr. expiration date/time	FFP, PLT	ALIQ
SPLIT into a bag	• Both products retain original expiration date/time	*Any product	SPLIT
RBC split to a syringe	• Original bag retains original expiration date/time. • New unit defaults to 24 hr. expiration date/time	RBC product	RBCSP

* The platelet parent bag retains the original outdate if maintained in the original gas permeable bag.

NOTE: Outdate must be adjusted if a closed system is not maintained.

3	TAB through today's date and time to enter the current time or enter the date and time when entering data from a Downtime Blood Component Prep Log.
4	• Verify the correct shift is entered in the Shift field • Enter any additional processing tech IDs (if applicable) • Click <Add> • Click <Continue>
5	Scan the unit # and component type in the appropriate fields **NOTE**: Although the component code may prefill after scanning the unit #, scanning of the component code is required to ensure the correct component is selected
6	Fill in any yellow fields in the Unit Data section of the window that are blank. **NOTE:** Notice the O and N on the left side of the screen. The O stands for the original unit, N stands for the new unit. The information displayed on the right side of the 

<table>
<tr><td></td><td>screen is the information for the highlighted piece. Both the O and N pieces need to be checked for blank yellow fields.

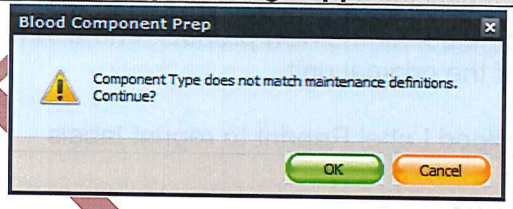
NOTE: Some processes will default to an appropriate expiration, but these fields should be checked for accuracy.
NOTE: When the volume for the N(ew) product is entered, the O(riginal) unit volume will automatically update</td></tr>
<tr><td>7</td><td>Verify the component expiration date/time is correct for both components
<table>
<tr><th>Process</th><th>Closed System Expiration</th><th>Open System Expiration</th><th>Product type</th></tr>
<tr><td>Aliquot into a syringe</td><td>• Original bag retains original expiration date/time.
• New product defaults to 4hr. expiration date/time</td><td>• Original bag expires in 24 hours
• New product expires in 4 hours

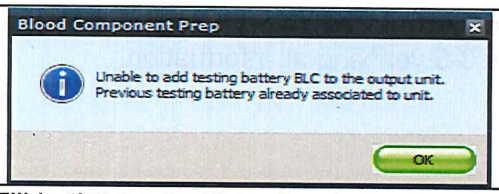
NOTE: Unless the original expiration is sooner</td><td>FFP, PLT</td></tr>
<tr><td>SPLIT into a bag</td><td>• Both products retain original expiration date/time</td><td>Both components expire in 24 hours unless the original expiration date is sooner.</td><td>*Any product</td></tr>
<tr><td>RBC split to a syringe</td><td>• Original bag retains original expiration date/time.
• New unit defaults to 24 hr. expiration date/time</td><td>Both components expire in 24 hours unless the original expiration date is sooner.</td><td>RBC product</td></tr>
</table>
* The parent bag retains the original outdate if maintained in the original gas permeable bag.

NOTE: Expiration dates/times <u>MUST ALWAYS</u> match or be shorter than the shortest outdate of the original unit or the modified unit.</td></tr>
<tr><td>8</td><td>Click <Save> when all entries are entered and verified</td></tr>
<tr><td>9</td><td>Click <Finish> when the preview output/new units box appears</td></tr>
<tr><td>10</td><td>Verify that two Labels printed. A full face label for the new product, and a ½ face (product/date) label for the remainder of the original unit

NOTE: If no label prints, go to section Blood Label Reprint to reprint labels</td></tr>
<tr><td>11</td><td>• Verify all information is accurate
• Place the new labels on the appropriate units
<table>
<tr><th>If label is a</th><th>Then</th></tr>
<tr><td>Full face</td><td>Go to next step</td></tr>
<tr><td>Half face</td><td>Draw a line through the supplier license #</td></tr>
</table></td></tr>
<tr><td>12</td><td>Perform a label check. See Blood Label Check Below.</td></tr>
</table>

Reconstituting Products:

STEP	ACTION
1	Select a non-irradiated RBC component with E code E0382, E4544 or E4545 **NOTE**: Due to a limitation in Sunquest, the Units will be physically packed, reconstituted with plasma, then irradiated prior to any computer manipulation
2	Select an appropriate thawed Plasma product
3	Open Blood Component Preparation (BCP) in Sunquest
4	Enter RWB in the Value Field
5	Press TAB to advance to the Date Field, if the date is today, Press TAB to default to today's date, otherwise enter the date of processing
6	Press TAB. The Cursor moves to the Time field, press TAB to default to current time, otherwise enter the time of processing. Cursor will move to the Shift Box.
7	• Verify the correct shift is entered in the Shift field • Enter any additional processing tech IDs (if applicable) • Click <Add> Click <Continue>
8	• First scan the Thawed PLASMA unit # in the unit # field. The cursor will move to the next field. • Scan the component code in the component field **Note**: Although the component code may prefill, scanning of the component code is required to ensure the correct component is selected.
9	• Scan the RBC unit # in the unit # field. The cursor will move to the next field • Scan the component code in the component field. **NOTE**: Although the component code may prefill, scanning of the component code is required to ensure the correct component is selected.
10	One of two messages will appear: **If following message appears:**  **Then** Review the input and process codes to verify both are correct **If information is** / **Then** Incorrect: Click <Cancel> and correct the error New input component needs to be added to the LIS: • Click <Cancel> • Refer to a MLS Lead for resolution • Complete a QI document to added component to LIS

		• Click 'OK' • This is a reminder to perform the label check following the product modification.
11	Fill in the reconstituted product volume in the Unit Data section	
12	Verify the new expiration date/times are correct **NOTE:** The new unit expiration date/time should be 24 hours or the expiration date/time of the original products used if <24 hours	
13	Click <Save> when all entries are verified.	
14	Click <Finish> when the review output/new units box appears.	
15	• Retrieve the half face (product/date) label **NOTE:** If no label prints, go to section Blood Label Reprint to reprint labels	
16	• Verify all information is accurate • Place the new labels on the appropriate unit	

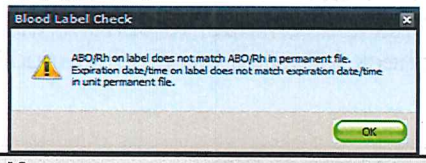
If label is a	Then
Full face	Go to next step
Half face	Draw a line through the supplier license #

17	Perform a label check (go to section Blood Label Check)

Blood Label Check:

STEP	ACTION
1	Open 'Blood Label Check' in Sunquest
2	Scan the unit # and component type in the appropriate fields **NOTE**: Although the component code may prefill after scanning the unit #, scanning of the component code is required to ensure the correct component is selected
3	Click <Search> **NOTE:** Unit information will populate the middle section of the screen. Mandatory fields will be highlighted in yellow.
4	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 date field and scan the expiration date/time barcode from the unit label
6	Click <Check Label>

If	Then
Label is correct	The screen will refresh to a new screen with unit #, component and division # retained
A discrepancy occurred during the check.	A warning will appear explaining the discrepancy and the label will not be checked.

	EXAMPLE:  	Click OK, resolve the discrepancy and repeat steps 3-6 verifying all information.

	If	Then
8	Product was divided, split or aliquoted	Both Products need to be label checked. Repeat steps 3-8 for the remaining product.
	No divisions were made	Label check is complete.

	If	Then
9	No containers, solutions or welds used in modification **EXAMPLE:** Thawing and irradiation do not require **additional test to track lot number**	Process is complete
	New containers, solutions or welds were used in modification	Go to the next section Adding Unit Testing in BOP

Adding Unit Testing in BOP (MLS only):

STEP	ACTION
1	Open 'Blood Order Processing' in Sunquest **NOTE:** This step is not required for processing that did not require additional supplies to be added to the product such as irradiation and thawing
2	Open the appropriate patient accession and allocate the unit (if not already performed)
3	Highlight the unit that was modified in the 'Compatibility Testing' window **NOTE**: When adding testing on a divided product, the testing should be added to the daughter unit, not the mother unit.
4	Add the following tests in the 'Add Unit Test (x)' window (as appropriate to the process performed):

If	Then
Adding Lot Number test	• Type ;LOTNO • Type ;; lot # and expiration. In the highlighted box. **EXAMPLE:** ;; 987654 exp. 11/17 **NOTE:** If more than one supply was used, <tab to enter each supply on a new line • Press <Tab>
Adding Weld Check test	• Type ;WELD

If	Then Enter	
Weld Passed	Code	Sunquest Hot Key
	WELDP	{
Weld	Code	Sunquest Hot Key

		Failed: WELDF } Modify the expiration date/time accordingly for open system (4 hrs. for platelets, 24 hrs. for RBC and FFP)
	Adding Hemolysis Check	• Type ;HEMO **If** / **Then Enter**: No Hemolysis → Code: HEMNO, Sunquest Hot Key: Y; Hemolysis Present → Code: HEM, Sunquest Hot Key: M
	Adding a supply lot #	**Test (Order)** / **Test Description** / **Enter**: SOLLOT / Solution Lot Number / Saline lot number; LOTNO / Supply Lot Number / Transfer pack, filter syringe, cell processing set **NOTE:** Type ;; and free text the supply lot number and Exp. *EXAMPLE: ;; 987654 exp. 11/17* **NOTE:** if using more than one supply, Tab to enter each supply on a new line. • Press Tab
5	Click <Save> when all testing is complete	

Blood Label Reprint:

STEP	ACTION
1	Open 'Blood Bank Label Print' function in Sunquest
2	**If printing a** / **Then select**: Full face label → Full Face in the Label type box at the top of the screen; Half face label → Product/Date in the Label type box at the top of the screen
3	Enter the number of labels needed in the 'Num. of copies' drop down box (defaults to 1)
4	Scan or type the unit number in the Unit # box
5	Scan the product code in the component box. **NOTE**: Although the component code may prefill after scanning the unit #, scanning of the component code is required to ensure the correct component is selected
6	Click <Add>
7	Repeat steps 3-6 if additional labels of the same type need to be printed.
8	Click <Print> when all units are entered to print the labels
9	Click <Exit> to close Blood Bank Label Print

PROCEDURE NOTES AND LIMITATIONS:

- Divided units may be physically separated once the both components have been relabeled and the label check performed and found to be acceptable
- 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.
- Testing for Lot number and weld cannot be added to units after splitting in Blood Product Testing, Blood Order processing must be used to record these results.

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 Dividing Blood Components
SOP Packing RBC and Reconstituting Whole Blood
SOP Reconstituting Whole Blood
SOP Volume Reduction of Platelets
SOP Washing RBC Components
SOP Washing Platelet Components
SOP Irradiating Blood Components
SOP Combining Double-Bag Apheresis Platelets

UWMC SOP Approval:

UWMC CLIA Medical Director	Mark H. Wener, MD	Date
Transfusion Service Manager	Deanne Stephens	Date
Compliance Analyst	Christine Clark	Date
Transfusion Service Medical Director	Monica B. Pagano, MD	Date

UWMC Biennial Review:

Date

Date

REVISION HISTORY:
04/22/2018: Revised for the Sunquest 8.1 upgrade. The system now contains logic to calculate accurate expiration dates when component processing is performed or will fire QA failures for expiration dates requiring manual correction by the processing staff member.

APPENDIX:

Appendix A: Job Aid

PROCESS	ACTION	
Thawing or Irradiating	Verify modified expiration date is not longer than original expiration date	
	Mark out US license #	
	Perform Label Check	
Washing	Verify modified expiration date is not longer than original expiration date	
	Perform Label Check	
	Allocate the unit to the patient	
	Add the following unit testing in BOP: **;LOTNO** — Enter lot # and expiration for cell processing set **;HEMO** — Enter Y for no or M for yes **;SOLLOT** — Enter lot# and expiration for saline	
Volume Reducing	Verify modified expiration date is not longer than original expiration date	
	Mark out US license #	
	Perform Label Check	
	Allocate the unit to the patient	
	Add the following unit testing in BOP: **;LOTNO** — Enter lot# expiration for attached bag (if necessary) **;WELD** — Enter { (Weld Passed) or } (Weld Failed)	
Combining Double Bagged Platelets	Verify modified expiration date is not longer than original expiration date	
	Mark out US license #	
	Perform Label Check	
Dividing Blood Products	Verify modified expiration dates are not longer than original expiration date	
	Mark out US license # on parent bag	
	Perform label check prior to disconnecting units	
	Allocate the unit to the patient	
	Add the following unit testing in BOP: **;LOTNO** — Enter lot # and expiration for new bag or syringe **;WELD** — Enter { (Weld Passed) or } (Weld Failed)	
Reconstitute Whole Blood	Allocate the unit to the patient and perform required crossmatch	
	Verify modified expiration date is not longer than original expiration date	
	Mark out US license # if applicable	
	Perform Label Check	
	Add the following unit testing in BOP: **;WELD** — Enter { (Weld Passed) or } (Weld Failed) **;LOTNO** — • Enter lot # and expiration for transfer bag used for plasma/supernatant removal • Enter lot # and expiration of plasma transfer set • Enter lot # and expiration date for pedi-pack bags	