University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA 98195 Transfusion Services Laboratory Policies and Procedures Manual	Original Effective Date: 10-28-20 Revision Effective Date:	Number: PC-0082.01

TITLE: **LIS Downtime Blood Component Labeling**

PURPOSE:
To describe the procedure for printing ISBT labels and relabeling blood components following modifications during LIS Downtime using the HemaTrax Blood and Blood Component Stand-alone Labeling Application and Digi-Trax ZM400 printer

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

PRINCIPLE & CLINICAL SIGNIFICANCE:
Principle
FDA standards for the labeling of blood products must continue to be met during LIS computer outages and other times when labels are printed using the non-interfaced stand-alone Digi-Trax ZM400 printer. The stand-alone HemaTrax system meets the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT-128 format.

Clinical Significance
Consistency in labeling maintains regulatory compliance and helps to ensure the safety of the transfusion process by allowing the nursing bedside verification of the blood product label to remain unchanged.

POLICIES:
- A second person must verify accurate relabeling of blood components when Sunquest Blood Label Check is not available.
- Divided components requiring relabeling of the original parent product
- The original Donor Identification Number (DIN) must remain visible when relabeling the component. Never cover over the original DIN with a new label.

SPECIMEN REQUIREMENTS:
NA

REAGENTS/SUPPLIES/EQUIPMENT:

Reagents:	Supplies:	Equipment:
None	• HemaTrax printer labels • Printer ribbons	• Dedicated PC with integrated stand-alone HemaTrax printer • Bar-code scanner

QUALITY CONTROL:
NA

INSTRUCTIONS:

TABLE OF CONTENTS:

Printing HemaTrax Labels

Step	Action
1	Log into the HemaTrax computer using the following username and password • Username: **hematrax** • Password: **D1G1Trax**
2	Click on <HemaTrax Unity Client> on the desktop using the following username and password • Username: **hematrax** • Password: **hematrax**
3	Select the "Full Face (4x4)" format from the "Select label" drop down box
4	Select the 'Zebra' printer from "Select printer" drop down box
5	Check the "Set to Scan Mode" in the upper left
6	**If component is** / **Then** NOT divided: • Go to next step Divided component: • Check the divided unit box • Enter aliquot letters for Division 1 and Division 2
7	**If relabeling** / **Then** **Original container with a label: • Cross out the supplier license number on the modified component** New container without a label: • Go to next step
8	**Quadrant I: DIN** • Click on the QI square • Click in the 'Facility ID Number" field and scan DIN barcode from the label **If** / **Then** Scanner fails: Manually key in the following from the DIN • Facility ID number (WXXXX) • Collection year (XX) • Serial number/unit number (XXXXXX) • Check the "Include Check Digit" box • Click <OK>

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>9</td><td>Quadrant II: ABO Blood Group/Rh Factor

• Click on the QII square
• Select the blood type for new label
• Select the appropriate donation type from the ‘Intended use’ drop down box
  ○ Volunteer Allogeneic Donation
  ○ Autologous Use Only
• Click <OK></td></tr>
<tr><td>10</td><td>Quadrant III: Product Code:

• Click on the QIII square
• Enter the component output E-code based on the initial product E-code and the modification performed - refer to Appendix 1: Blood Component Prep E-codes
• Click <OK>

NOTE: The output component Ecode can be found by entering information about the product category e.g. anticoagulant, draw volume, additive solution and clicking the search key.</td></tr>
<tr><td>11</td><td>Quadrant VI: Expiration date and time:

• Click on the QIV square
• Select the correct Expiration option
<table>
<tr><th>If expiration time is</th><th>Then click on</th></tr>
<tr><td>Midnight or 23:59</td><td>“Expiration date only”</td></tr>
<tr><td>NOT midnight</td><td>“Expiration date and Time”</td></tr>
</table>
• Manually enter the correct new expiration date and time

Special test field:
• Select any special test from the choices
• Click <OK>

Processing Facility Box:
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>No additional processing</td><td>Go to next step</td></tr>
<tr><td>Addition processing performed</td><td>• Enter the facility code in the box under “Facility World Code”, W2584 is for UWMC
• Select “Further Processing By” from “Processing Legend” drop down
• Check box to include FDA registration number</td></tr>
</table>
• Click <OK></td></tr>
<tr><td>12</td><td>Click <PRINT> to print a single label</td></tr>
</table>

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>13</td><td>Verify the label accuracy by comparing printed label to original product label and verifying all information is correct (E-code, product type, expiration date/time, volume and division codes)
<table>
<tr><th>If information is</th><th>Then</th></tr>
<tr><td>Correct</td><td>Go to next step</td></tr>
<tr><td>Incorrect</td><td>Update any fields as necessary and reprint the label</td></tr>
</table></td></tr>
<tr><td>14</td><td>
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>No additional label is needed</td><td>• Exit the program and log out</td></tr>
<tr><td>Label for a different component type is needed</td><td>• Select “All Quadrants” in the “Clear Quadrants” box in the bottom left
• Click <Clear>
• Repeat steps 8 thru 14</td></tr>
<tr><td>Additional label of the same component type is needed</td><td>• Follow steps 7 thru 14 as required making any needed changes such as volume</td></tr>
</table></td></tr>
<tr><td>15</td><td>Go to section Blood Label Check

IMPORTANT: Do not relabel the component until a second tech verifies the label is accurate</td></tr>
</table>

Blood Label Check

Step	Action
1	Obtain the *Component Prep Downtime Log* and ensure all information under the Input and Prep sections are complete
2	Ensure all required information in the Output section is complete except for “Label Verified By 2nd Tech”
3	Ask a second trained staff member to perform and document a Blood Label Check following steps 4 thru 8 below
4	Verify the following information is identical on the original and new labels: • Unit Number • ABO/Rh
5	Verify that the following are accurate for the output product label based on the modification performed: • Product description and component code (Ecode) (refer to Appendix A: Blood Component Prep E-codes) • Expiration date/time • Product Volume • Division code, when applicable
6	Verify the collection facility and the modifying facility (Further Processed By:) are accurate and the license number of the collection facility is crossed out **NOTE:** University of Washington Medical Center should always be selected as the modifying facility

Step	Action
7	Affix label to cover previous label without covering the original DIN
8	Have the 2nd verifier initial the 'Verified By 2nd Tech' box on the *Component Prep Downtime Log* to indicate the component is labeled correctly

CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL
NA

VALUES/CRITICAL VALUES:
NA

CALIBRATION:
NA

NOTES AND LIMITATIONS:
- HemaTrax tracks the activities of every user from the time they log-on to log-off
- The stand-alone HemaTrax database is populated with product labels defined in the International Council for Commonality in Blood Banking Automation (ICCBBA) product table and must be updated periodically to remain current
- The "clear quadrants" button can be used to facilitate removal of prior unit information prior to creating additional labels

REFERENCES:
- Hematrax Blood and Blood Component Stand Alone Labeling Application Version 6.2.1
- Standards for Blood Banks and Transfusion Services, American Association of Blood Banks, Bethesda, MD. Current Edition.

RELATED DOCUMENTS:
FORM *Component Prep Downtime Log*
FORM *Irradiation Downtime Log*

APPENDIX:
Appendix 1: Blood Component Prep E-codes (see attached separate document)

UWMC SOP Approval:

UWMC CLIA Medical Director	Mark H. Wener, MD	Date 10/20/20
Transfusion Service Manager	Nina Sen	Date 10/16/20
Compliance Analyst	Christine Clark	Date 10.16.2020
Transfusion Service Medical Director	Monica Pagano, MD	Date 10-19-2020

UWMC Biennial Review:

	Date
	Date