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| <b>University of Washington Medical Center</b><br><b>1959 NE Pacific Street. Seattle, WA 98195</b><br><b>Transfusion Services Laboratory</b><br><b>Policies and Procedures Manual</b> | <b>Original Effective Date:</b><br><b>05-23-2022</b> | <b>Number:</b><br><b>DR-0003.01</b> |
|   | <b>Revision Effective Date:</b>                      |                                     |
| <b>TITLE: New and Revised Blood Bank Labels</b>   |  |                                     |

**PURPOSE:**

For requesting, creating and implementing new labels for blood bank

**PRINCIPLE & CLINICAL SIGNIFICANCE:**

**POLICIES:**

• **ISBT 128 Labels (blood component)**

- Are labeled with ISBT 128 standard labels generated via the Laboratory Information System (LIS) or a standalone Hematrx
- University of Washington Medical Center (UWMC) Transfusion Service ISBT facility identification number is W2584
- Labels are printed on Hematrx enabled (ISBT128) Zebra label printers using Digitrax software interfaced with the LIS. A standalone printer is available for use during computer downtimes.
- LIS and Digitrax software is licensed by the UWMC Laboratory Medicine IT Department (Lab Med IT)
- The need for new or revised labels maybe due but not limited to the following:
  - New supplier product
  - New manufacturing process
  - Modification (secondary processing) of blood components
  - Regulatory changes
  - LIS changes and upgrades
- **Validation:**
  - Product codes (ecodes) and corresponding blood component labels are validated for accuracy as part of the LIS validation plan when new components are added to the system.
    - Validation includes both visual verification of accuracy and electronic verification of barcodes when changes affect barcoded information.
    - There may be instance where changes to the label that do not affect any other LIS processes and validation is only a visual confirmation for accuracy. In these cases, approval will be documented on the approved *Blood Component Label Form*
  - Validation will be performed in the LIS Test System

• **Labels other than ISBT 128 blood component**

- All labels are document controlled and the changes are not made unless approved by the TSL Operations and/or QA managers
- **Validation:** Labels are visually confirmed to be accurate with documentation on the corresponding *Approved Label Form*
- Refer to Appendix 1 *Blood Bank Labels Excluding ISBT 128 Labels* for list of approved blood bank labels

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**SPECIMEN REQUIREMENTS:**

NA

**REAGENTS/SUPPLIES/EQUIPMENT:**

| Reagents: | Supplies: | Equipment: |
|-----------|-----------|------------|
| NA        | NA        | NA         |

**QUALITY CONTROL:**

- Blood Component labels are visually and electronically (barcodes) verified as accurate prior to use.
- Any errors found after implementation should be documented on a *Quality Improvement* form and submitted to the TSL QA Manager.

**INSTRUCTIONS:**

**TABLE of CONTENTS (only if there are multiple sections)**

[Requesting New/ Revised ISBT 128 Labels](#)

[Validating New/ Revised ISBT 128 Labels](#)

[Requesting New/ Revised Labels other than ISBT128 Labels](#)

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[Appendix 1: Blood Bank Labels Excluding ISBT 128 Labels](#)

**Requesting New/Revised ISBT 128 Labels**

| STEP                              | ACTION   |                 |      |                        |                 |                                   |   |
|-----------------------------------|--|-----------------|------|------------------------|-----------------|-----------------------------------|---|
| 1                                 | Submit a request to Lab Med IT (listest@uw.edu) to add a new blood component to the LIS<br><br><b>NOTE:</b> This is usually done by the TSL Operations Manager but may be submitted by other staff working on some aspect of the change. Include TSL operations manager on any requests to Lab Med IT  |                 |      |                        |                 |                                   |   |
| 2                                 | Complete the BB Product and Component Prep Request Template provided by Lab Med IT <table border="1" data-bbox="302 1339 1430 1507"> <thead> <tr> <th>If completed by</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>TSL Operations Manager</td> <td>Go to next step</td> </tr> <tr> <td>Other than TSL Operations Manager</td> <td>Submit to TSL Operations Manager for Review</td> </tr> </tbody> </table> | If completed by | Then | TSL Operations Manager | Go to next step | Other than TSL Operations Manager | Submit to TSL Operations Manager for Review |
| If completed by                   | Then   |                 |      |                        |                 |                                   |   |
| TSL Operations Manager            | Go to next step  |                 |      |                        |                 |                                   |   |
| Other than TSL Operations Manager | Submit to TSL Operations Manager for Review  |                 |      |                        |                 |                                   |   |
| 3                                 | Submit the BB Product and Component Prep Request Template to Lab Med IT who will make the proposed changes to the Sunquest Maintenance Database<br><br><b>Note:</b> TSL Medical Director approval required   |                 |      |                        |                 |                                   |   |
| 4                                 | Go to section <a href="#">Validating New/ Revised ISBT 128Labels</a> once Lab Med IT has completed the build   |                 |      |                        |                 |                                   |   |

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### Validating New/ Revised ISBT 128 Labels

| STEP                      | ACTION   |                    |      |                           |                 |                 |   |
|---------------------------|--|--------------------|------|---------------------------|-----------------|-----------------|---|
| 1                         | Perform the appropriate Lab Med IT LIS validation plan including labels generated via the LIS and standalone Hematrax printer  |                    |      |                           |                 |                 |   |
| 2                         | Print two labels generated by the LIS and attach the 2 <sup>nd</sup> label on a <i>ISBT 128 Label Form</i> – one label is included with the LIS validation plan and the other in the ISBT 128 Label Binder   |                    |      |                           |                 |                 |   |
| 3                         | Submit the completed validation and to the TSL QA Manager for final review   |                    |      |                           |                 |                 |   |
|                           | <table border="1"> <thead> <tr> <th>If plan is</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Approved</td> <td>Go to step 5</td> </tr> </tbody> </table>  | If plan is         | Then | Approved                  | Go to step 5    |                 |   |
|                           | If plan is   | Then               |      |                           |                 |                 |   |
|                           | Approved   | Go to step 5       |      |                           |                 |                 |   |
| Not approved              | <table border="1"> <thead> <tr> <th>If issue is due to</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Performance of validation</td> <td>Go to next step</td> </tr> <tr> <td>IT build or LIS</td> <td>Notify Lab Med IT of the issue and work with them to resolve it</td> </tr> </tbody> </table> | If issue is due to | Then | Performance of validation | Go to next step | IT build or LIS | Notify Lab Med IT of the issue and work with them to resolve it |
|                           | If issue is due to   | Then               |      |                           |                 |                 |   |
| Performance of validation | Go to next step  |                    |      |                           |                 |                 |   |
| IT build or LIS           | Notify Lab Med IT of the issue and work with them to resolve it  |                    |      |                           |                 |                 |   |
|                           |  |                    |      |                           |                 |                 |   |
| 4                         | Repeat validation or portion of validation affected and submit to TSL QA Manager   |                    |      |                           |                 |                 |   |
| 5                         | TSL Operations Manager will coordinate time of implementation with Lab Med IT  |                    |      |                           |                 |                 |   |
| 6                         | Go to section <a href="#">Implementing New or Revised Labels</a>   |                    |      |                           |                 |                 |   |

### Requesting a New or Revised Labels other than ISBT 128 Labels

| STEP               | ACTION  |   |      |          |   |                    |                        |              |                   |
|--------------------|---|---|------|----------|---|--------------------|------------------------|--------------|-------------------|
| 1                  | Submit request to the TSL Operations Manager  |   |      |          |   |                    |                        |              |                   |
| 2                  | <table border="1"> <thead> <tr> <th>If</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Approved</td> <td>TSL Operations Manager will coordinate purchase of label or supplies if printed by UWMC TSL</td> </tr> <tr> <td>Revisions required</td> <td>Revisions will be made</td> </tr> <tr> <td>Not approved</td> <td>No further action</td> </tr> </tbody> </table> | If  | Then | Approved | TSL Operations Manager will coordinate purchase of label or supplies if printed by UWMC TSL | Revisions required | Revisions will be made | Not approved | No further action |
|                    | If  | Then  |      |          |   |                    |                        |              |                   |
|                    | Approved  | TSL Operations Manager will coordinate purchase of label or supplies if printed by UWMC TSL |      |          |   |                    |                        |              |                   |
| Revisions required | Revisions will be made  |   |      |          |   |                    |                        |              |                   |
| Not approved       | No further action   |   |      |          |   |                    |                        |              |                   |
| 3                  | Complete an <i>Approved Label Form</i> and submit to the TSL Manager  |   |      |          |   |                    |                        |              |                   |
| 4                  | Go to section <a href="#">Implementing New or Revised Labels</a>  |   |      |          |   |                    |                        |              |                   |

### Implementing New or Revised Labels

| 1            | <table border="1"> <thead> <tr> <th>If new or revised policy or procedures are</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Required</td> <td> <ul style="list-style-type: none"> <li>• Create or revise as appropriate</li> <li>• Submit to TSL Manager for approval</li> </ul> </td> </tr> <tr> <td>Not required</td> <td>Go to next step</td> </tr> </tbody> </table> | If new or revised policy or procedures are  | Then | Required | <ul style="list-style-type: none"> <li>• Create or revise as appropriate</li> <li>• Submit to TSL Manager for approval</li> </ul> | Not required | Go to next step |
|--------------|--|---|------|----------|---|--------------|-----------------|
|              | If new or revised policy or procedures are   | Then  |      |          |   |              |                 |
|              | Required   | <ul style="list-style-type: none"> <li>• Create or revise as appropriate</li> <li>• Submit to TSL Manager for approval</li> </ul> |      |          |   |              |                 |
| Not required | Go to next step  |   |      |          |   |              |                 |
|              |  |   |      |          |   |              |                 |
|              |  |   |      |          |   |              |                 |

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|   | If training is   | Then   |
|---|--|--|
| 2 | Required   | TSL manager will coordinate training with lead |
|   | Not required or not required to be completed prior to implementation | Go to next step                                |
| 3 | Implement use of new label   |  |

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

NA

**CALIBRATION:**

NA

**PROCEDURE NOTES AND LIMITATIONS:**

NA

**REFERENCES:**

NA

**RELATED DOCUMENTS:**

- FORM *Approved Label Form*
- FORM *ISBT 128 Label Form*
- FORM *Quality Improvement*
- Lab Medicine IT Blood Bank Validation Procedure

|   |                   |      |
|---|-------------------|------|
| <b>UWMC SOP Approval:</b>                           |                   |      |
| <b>UWMC CLIA<br/>Medical Director</b>               | Andrew Bryan, MD  | Date |
| <b>Transfusion<br/>Service Manager</b>              | Nina Sen          | Date |
| <b>QA Manager</b>                                   | Tayler Reeves     | Date |
| <b>Transfusion<br/>Service<br/>Medical Director</b> | Monica Pagano, MD | Date |
| <b>UWMC Biennial Review:</b>                        |                   |      |
|   |                   | Date |
|   |                   | Date |

**APPENDIX:****Appendix 1: Blood Bank Labels Excluding ISBT 128 Labels**

| DESCRIPTION                | MANUFACTURER    | ITEM #                    |
|----------------------------|-----------------|---------------------------|
| Uncrossmatched Blood       | UWMC TSL        | Avery #5477 (orange)      |
| Quarantined                | UWMC TSL        | Avery #5160 (pink)        |
| Do Not Refrigerate         | UWMC TSL        | Avery #5160( neon yellow) |
| HLA Selected Unit          | UWMC TSL        | Avery #5160               |
| 0.2M DTT Reconstituted     | UWMC TSL        | Avery #5160               |
| DTT Treated Screening Cell | UWMC TSL        | Avery #5160               |
| Saline Bottle              | UWMC TSL        | Avery #5160               |
| PSN                        | UWMC TSL        | Avery #5160               |
| Working Wash Solution      | UWMC TSL        | Avery #5160               |
| For Training Use Only      | UWMC TSL        | Avery #5160               |
| New Lot                    | UWMC TSL        | Avery #5160               |
| Use First                  | UWMC TSL        | Avery #5167               |
| Short Date                 | UWMC TSL        | Avery #5167               |
| Stat                       | United Ad Label | ULHT116 (supplied by SPS) |
| Name Alert                 | United Ad Label | HN116 (supplied by SPS)   |
| DI Water                   | UWMC TSL        | Avery #5160               |