University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA, 98195 Transfusion Services Laboratory Policies and Procedures Manual	Original Effective Date: 8/15/2022 Revision Effective Date:	Number: PE-0001.00

TITLE: **Training and Competency Assessment**

PURPOSE:

To describe the process for initial training, ongoing training, and assessment of competency of both testing personnel and personnel performing critical tasks. Prior to hire, employee's qualifications and credentials will be assessed by University of Washington (UW) Human Resources.

POLICIES:

Training:

- Initial training is conducted prior to a new employee reporting patient test results and, where applicable, encompasses pre-analytical (specimen collection, receipt, and processing), analytical (test performance) and post-analytical (result evaluation and reporting) phases of testing.
- Training may include but is not limited to the following:
  1. Reading relevant policies and procedures
  2. Observation of proper collection, labeling and processing of specimens
  3. Observation of test and/or task performance
  4. Hands-on training on the use of the computer system (proper accessioning, resulting and inquiry)
  5. Hands-on training on the use of equipment
  6. Hands-on training with patient samples, quality control samples, proficiency samples or blind samples
- As new instruments and/or analytical procedures are introduced, personnel will receive documented training prior to performing critical tasks, and/or tests. All ongoing training will be documented in each employee's training folder.
- Additionally, training will be provided and documented as part of the corrective action process in the event of failed proficiency testing or if deemed necessary after a non-conforming event.

Competency Assessment:

- After testing personnel have been trained and are performing tasks independently, competency is assessed semi-annually i.e., at 6-months and 1-year after training is completed. After the first year, a reassessment of competency is annual and includes all testing personnel.
  - Critical Task competency will be assessed before the employee performs tasks independently and will be reassessed annually.
  - Semi-annual assessment is not required for current employees trained on new methods or instruments.
- Retraining and reassessment of competency must occur if the competency is not satisfactory. Additionally, if testing personnel fail to demonstrate satisfactory performance on the competency assessment, a corrective action plan will be used to retrain and reassess competency.

- Competency assessments for moderate and high complexity tests will include six assessment elements for each test system and for each employee.
- For waived test systems and critical tasks, only the competency assessment elements applicable to the process will be used.
- Competency assessment elements include, but are not limited to:
    1. Direct observation (DO) of routine patient test performance
    2. Monitoring the recording and reporting of test results.
    3. Review of intermediate test results/worksheets, quality control records, proficiency testing results and preventive maintenance records.
    4. Direct observations of performance of instrument maintenance and function checks.
    5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
    6. Assessment of problem-solving skills.
- **Direct Observation:**
    - A Direct Observation task list for each test system is outlined in Appendix A, if a step is not performed or is performed incorrectly during a direct observation, the step number designated in this policy will be documented on the appropriate area of the competency assessment form.
    - Personnel performing direct observations for high complexity testing must meet the CAP (College of American Pathology) requirements for general supervisor and are delegated in writing by the section director (per CAP GEN.55500).

Performance Assessment of Managers:

- Responsibilities of Managers (Technical Supervisors, Technical consultants, General supervisors) are delegated in writing per Policy ***TSL Medical Director Designation of Record Review***
- Performance assessment will occur annually in line with UW performance evaluation season.
- Unsatisfactory performance will be addressed in a corrective action plan or performance improvement plan.
- Individuals performing non-waived patient testing will complete competency assessment requirements for testing personnel.

INSTRUCTIONS:

Training:

- New employees are to complete the Initial Training Checklist appropriate for their role.
- The date documented for “Date Trained” on the Initial Training Checklist should indicate the date that training is completed, and the employee is ready for Competency Assessment.
- If an employee will not be trained on an item listed on the training checklist, **NPBE** (Not Performed by Employee) will be documented in the “Date Trained” field for that task.
- It is the trainee’s responsibility to communicate which tasks remain on their checklist with the trainer to ensure that all checklist items are completed.

Competency Assessment:

- See **Appendix A** for Direct Observation Critical Step Lists

- If a task/test will not be performed by an employee, it will be documented on the competency assessment form by answering "No" to the question "Is this task performed by this employee?" AND indicating "C" in the "Competency Level" box.
- **Initial Competency Assessment** will require the minimum number of blind testing samples outlined below:

Tests	Minimum # Blind Samples	Comments
Ortho Vision	1	
ABO/Rh	5	
Antibody Screen	5	
Crossmatch	5	(At least 1 of each of the following: • Electronic Crossmatch • Immediate Spin Crossmatch • LISS Crossmatch • PEG Crossmatch
Direct Antiglobulin Test (DAT)	5	At least 2 positives
Antibody Identification	5	
Antigen Typing	1	Patient or Donor sample
Fetal Maternal Hemorrhage RapidScreen	1	
Sickledex Hemoglobin S	1	
Testing with DTT treated cells	1	
EGA	1	
Eluate	1	

- **Subsequent (Semi-annual and Annual) Competency Assessment** will require a single blind sample for each test listed above. CAP survey specimens or selected samples may be used.

REFERENCES:

AABB Standards for Blood Banks and Transfusion Services, AABB Press
CAP Checklists- General, All Common, Transfusion Medicine
AABB Technical Manual, AABB Press

RELATED DOCUMENTS:

SOP TSL Medical Director Designation of Record Review (OR-0002.02)
Form Initial Training Checklist - Clinical Laboratory Technician (TC-0006.00)
Form Initial Training Checklist - Medical Laboratory Scientist (TC-0007.00)
Form Transfusion Services Critical Task Competency Assessment (TC-0004.00)
Form Transfusion Services Testing Personnel Competency Assessment (TC-0005.00)
Form ABORh and Antibody Screen Initial Competency Assessment Blind Testing (TC-0001.00)
Form Crossmatch Initial Competency Assessment Blind Testing (TC-0002.00)
Form DAT Initial Competency Assessment Blind Testing (TC-0003.00)

UWMC SOP Approval:			
UWMC CLIA Medical Director	_____		_____
	Andrew Bryan, MD	Date	
Transfusion Service Manager	_____	Date	_____
	Nina Sen		
QA Manager	_____	Date	_____
	Tayler Reeves		
Transfusion Service Medical Director	_____	Date	_____
	Monica Pagano, MD		
UWMC Biennial Review:			
	_____	Date	_____
	_____	Date	_____

Appendix A – Direct Observation Critical Steps

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<table>
<tr><th colspan="2">Specimen Receipt and Processing – Interfaced Orders</th></tr>
<tr><td>1</td><td>Confirm specimen is:
• Collected in correct container
• Labeled with Name, MRN, draw date, draw time, and 2 signatures</td></tr>
<tr><td>2</td><td>Open Blood Bank Inquiry</td></tr>
<tr><td>3</td><td>Select Lookup by ‘Patient ID’ and enter the patient medical record number (MRN)</td></tr>
<tr><td>4</td><td>Determine if the patient has multiple HID
<table>
<tr><th>If the Patient has</th><th>Then</th></tr>
<tr><td>Only a “U” HID</td><td>Go to the next step</td></tr>
<tr><td>“H” and “U” HID</td><td>Select the U HID</td></tr>
</table></td></tr>
<tr><td>5</td><td>Open General Laboratory in Sunquest</td></tr>
<tr><td>6</td><td>Click on ‘Orders’ and select <Orders Receipt/Modify></td></tr>
<tr><td>7</td><td>Enter/Scan the CID or MRN from the specimen</td></tr>
<tr><td>8</td><td>Click <Get Patient></td></tr>
<tr><td>9</td><td>Click <Display Orders>
NOTE: It might be necessary to change the Day(s) of Activity</td></tr>
<tr><td>10</td><td>Update/enter the collection information
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Collection time on the tube is different from SQ</td><td>Update SQ to match the tube</td></tr>
<tr><td>There is a Tech ID for the Phlebotomist</td><td>•Enter: VP in the Order Workload Code field
•Enter the Tech ID in the Phlebotomist Code field</td></tr>
</table></td></tr>
<tr><td>11</td><td>
<table>
<tr><th>If the sample has a(n)</th><th>Then</th></tr>
<tr><td>SQ label</td><td>•Click <Receive>
•Verify checkmark X is next to the CID number that is the same as the labeled specimen
•Click <SAVE></td></tr>
<tr><td>EPIC ADT label</td><td>•Update the container type, if necessary
•Click <Route>
•Click <SAVE> when Result Entry Box appears.</td></tr>
</table></td></tr>
<tr><td>12</td><td>
<table>
<tr><th>If the Result Entry Box</th><th>Then</th></tr>
<tr><td>Has a units ordered field</td><td>Enter the units ordered</td></tr>
<tr><td>Does not have a units ordered field</td><td>Continue to the Next Step</td></tr>
</table></td></tr>
<tr><td>13</td><td>Click <Save></td></tr>
</table>

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<table>
<tr><th colspan="2">Issuing Blood Components</th></tr>
<tr><td>1</td><td>Timestamp the Blood Product Release Form</td></tr>
<tr><td>2</td><td>
<table>
<tr><th>If issuing a unit that was</th><th>Then</th></tr>
<tr><td>Previously allocated</td><td>• Open Blood Product Issue
• Scan or enter the MRN from the Blood Product Release Form
• Input component group based on Blood Product Release Form
• Choose the appropriate unit to issue from storage location</td></tr>
<tr><td>Not Previously allocated</td><td>• Open Blood Order Processing
• Scan or enter the MRN from the Blood Product Release Form
• Allocate a unit
• Click <SAVE>
• Click <ISSUE></td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Time stamp or manually record date and time the Transfusion Record</td></tr>
<tr><td>4</td><td>Verify unit meets all the patient transfusion requirements

Note: All red cells, granulocytes and non pathogen reduced platelets must be irradiated</td></tr>
<tr><td>5</td><td>Scan unit and product code in Sunquest</td></tr>
<tr><td>6</td><td>Perform visual inspection for the following:
• Expiration date has not passed
• Correct Labeling
• Intact Container
No Clots, turbidity, hemolysis or other abnormal appearance of the component</td></tr>
<tr><td>7</td><td>Document in Sunquest</td></tr>
<tr><td>8</td><td>Verify patient and component information matches on the transfusion record, Blood Product Release From, ISBT label, and Sunquest</td></tr>
<tr><td>9</td><td>Click <Continue></td></tr>
<tr><td>10</td><td>Complete issue in Sunquest</td></tr>
<tr><td>11</td><td>Click <Save> and click <Cancel> in the Add Billing window</td></tr>
<tr><td>12</td><td>Give unit to second staff member to perform clerical check of Unit label and Transfusion Record</td></tr>
</table>

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<table>
<tr><th colspan="2">Irradiating Blood Components</th></tr>
<tr><td>1</td><td>Date and initial a Rad-Sure indicator label and adhere to component without obliterating other required labeling elements</td></tr>
<tr><td>2</td><td>Verify key is in “cycle” mode on the irradiator</td></tr>
<tr><td>3</td><td>Open the RSTScan program</td></tr>
<tr><td>4</td><td>Scan the following into the appropriate field on the tablet
<table>
<tr><th>Field</th><th>Scan</th></tr>
<tr><td>User ID</td><td>User ID badge (this is only scanned once for each batch of components)</td></tr>
<tr><td>Indicator Batch ID</td><td>Rad-Sure XR 25 Gy Indicator label Batch ID (Lot number)</td></tr>
<tr><td>Product Code</td><td>Product Code</td></tr>
<tr><td>Donor ID</td><td>Donor Unit Number</td></tr>
</table></td></tr>
<tr><td>5</td><td>Select ‘Add’ to populate the chart below the data fields for each unit added to the batch</td></tr>
<tr><td>6</td><td>Scan all units that will be irradiated in one batch</td></tr>
<tr><td>7</td><td>Load the unit into the canister</td></tr>
<tr><td>8</td><td>Load canister into canister holder with lid facing out</td></tr>
<tr><td>9</td><td>Close the chamber door</td></tr>
<tr><td>10</td><td>Start the cycle by pressing the “Start” button</td></tr>
<tr><td>11</td><td>Press “Door Release” when buzzer sounds</td></tr>
<tr><td>12</td><td>Remove product and close chamber door</td></tr>
<tr><td>13</td><td>Enter Rad-Sure indicator result into RSTScan program</td></tr>
<tr><td>14</td><td>Save data</td></tr>
<tr><td>15</td><td>Use Blood Component Preparation in Sunquest and choose correct function based on the product’s E code</td></tr>
<tr><td>16</td><td>Enter the correct new expiration date/time in Sunquest (28 days from date of Irradiation or original expiration if shorter)</td></tr>
<tr><td>17</td><td>Place new label on product</td></tr>
<tr><td>18</td><td>Verify that the US license number is obscured or mark out the license number</td></tr>
<tr><td>19</td><td>Perform Blood Label Check in Sunquest</td></tr>
<tr><td>20</td><td>Place product in correct storage location in a timely manor</td></tr>
</table>

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<table>
<tr><th colspan="2">Thawing Frozen Blood Components</th></tr>
<tr><td>1</td><td>Select an appropriate unit to thaw</td></tr>
<tr><td>2</td><td>Examine the product for defects and ensure unit is not expired</td></tr>
<tr><td>3</td><td>Place the product in an overwrap bag, ports up</td></tr>
<tr><td>4</td><td>Check water level and temperature is between 30-37°C</td></tr>
<tr><td>5</td><td>Place the bag in the thaw bath basket attaching the overwrap bag to the basket</td></tr>
<tr><td>6</td><td>Select an appropriate thawing time for the selected product following these guidelines:
<table>
<tr><th>If Component is</th><th>Median Thaw Time (minutes) is</th></tr>
<tr><td>≈ 10-15 mL cryoprecipitate</td><td>5</td></tr>
<tr><td>Pooled cryoprecipitate ≈ 250 mL</td><td>8</td></tr>
<tr><td>≈ 250 mL plasma</td><td>10</td></tr>
<tr><td>≈ 300 mL plasma</td><td>14</td></tr>
</table></td></tr>
<tr><td>7</td><td>Start cycle</td></tr>
<tr><td>8</td><td>Examine product at the end of the cycle, verify no leaks and unit thawed correctly</td></tr>
<tr><td>9</td><td>Use Blood Component Preparation in Sunquest and choose correct function based on the product’s E code</td></tr>
<tr><td>10</td><td>Verify the expiration date and time is accurate</td></tr>
<tr><td>11</td><td>Verify the label information is correct and place new label on the unit</td></tr>
<tr><td>12</td><td>Perform Blood Label Check in Sunquest</td></tr>
</table>

Combining Double Bagged Apheresis Platelets	
1	Select the bag with the complete labeling (ISBT label including attached tags and additional stickers if applicable) as the final product container **NOTE:** Labeling of double bag products may vary by blood supplier
2	Hold or hang the bag to be discarded higher than the bag selected as the final product container
3	Open any slider valve or clamp between the bags
4	Allow the upper bag to drain into the final container by gravity
5	Heat seal the tubing between the two bags
6	Modify the expiration date/time to 24 hours or the original expiration date/time whichever is shorter in the BB LIS

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<table>
<tr><th colspan="2">Dividing Blood Components</th></tr>
<tr><td>1</td><td>Mix the blood product prior to dividing</td></tr>
<tr><td>2</td><td>Tighten the tubing on the syringe, remove spike and clip</td></tr>
<tr><td>3</td><td>Check the weld count on the Sterile Welder</td></tr>
<tr><td>4</td><td>Follow directions on Sterile Welder</td></tr>
<tr><td>5</td><td>Remove tubing and discard stubs</td></tr>
<tr><td>6</td><td>Inspect Weld for leaks and check integrity of weld by gently pulling and squeezing tubing</td></tr>
<tr><td>7</td><td>Press Reset on the sterile welder</td></tr>
<tr><td>8</td><td>Draw required volume plus 3-5 ml of blood into the syringe</td></tr>
<tr><td>9</td><td>Seal the tubing</td></tr>
<tr><td>10</td><td>Perform modification in Sunquest</td></tr>
<tr><td>11</td><td>Verify new label matches the original unit expiration and product code and adhere label to the unit</td></tr>
<tr><td>12</td><td>Verify large label unit number matches the original unit, the unit expiration date and product code are correct and place on syringe</td></tr>
<tr><td>13</td><td>Perform Blood Label Check in Sunquest</td></tr>
<tr><td>14</td><td>Cut the syringe from the bag carefully</td></tr>
<tr><td>15</td><td>Aseptically remove the stub end from the syringe and replace with a sterile cap</td></tr>
<tr><td>16</td><td>Irradiate the blood product</td></tr>
<tr><td>17</td><td>Perform Irradiation in Sunquest- Label and Label Check unit</td></tr>
<tr><td>18</td><td>
<table>
<tr><th>If employee is</th><th>Then</th></tr>
<tr><td>MLS</td><td>• Allocate unit to correct patient
• Add LOTNO and WELD to unit testing
• Result testing</td></tr>
<tr><td>CLT</td><td>Continue to the next step</td></tr>
</table>
</td></tr>
<tr><td>19</td><td>Replace units in correct storage locations</td></tr>
</table>

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<table>
<tr><th colspan="2">Volume Reduced Platelets</th></tr>
<tr><td>1</td><td>Use the SCD Rapidweld to add a transfer pack of the appropriate size to the unit prior to centrifugation (if necessary)</td></tr>
<tr><td>2</td><td>Inspect Weld for leaks and check integrity of weld by gently pulling and squeezing tubing</td></tr>
<tr><td>3</td><td>Clamp the tubing between the product bag and transfer pack prior to centrifugation</td></tr>
<tr><td>4</td><td>Balance the centrifuge cups prior to loading the centrifuge</td></tr>
<tr><td>5</td><td>Load the product with ports up and product label facing outward</td></tr>
<tr><td>6</td><td>Select the correct program for the modification being performed and verify temperature requirements are met</td></tr>
<tr><td>7</td><td>Document centrifuge QC on the Refrigerated Centrifuge QC log</td></tr>
<tr><td>8</td><td>Remove product without disturbing the platelet pellet</td></tr>
<tr><td>9</td><td>Hang or insert Platelet unit into plasma extractor</td></tr>
<tr><td>10</td><td>Tare scale with empty bag and remove all but 100 ml from the component or alternate volume if specifically requested</td></tr>
<tr><td>11</td><td>Heat seal off waste bag and perform modification in Sunquest</td></tr>
<tr><td>12</td><td>Use Blood Component Preparation in Sunquest and choose correct function based on the product’s E code</td></tr>
<tr><td>13</td><td>Use the date and time that plasma expression began as the process date and time</td></tr>
<tr><td>14</td><td>Enter the new volume and verify the expiration date and time is accurate</td></tr>
<tr><td>15</td><td>Verify the label information is correct and place new label on the unit</td></tr>
<tr><td>16</td><td>Perform Blood Label Check in Sunquest</td></tr>
<tr><td>17</td><td>Discard waste bag</td></tr>
<tr><td>18</td><td>Allow component to rest undisturbed for 20 minutes and resuspend the component</td></tr>
<tr><td>19</td><td>Place component on platelet agitator for 20 minutes and inspect
<table>
<tr><th>If component is</th><th>Then</th></tr>
<tr><td>Acceptable</td><td>Continue to the next step</td></tr>
<tr><td>Not acceptable</td><td>• Break up large aggregates with gentle finger pressure
• Agitate for an additional 20 minutes</td></tr>
</table></td></tr>
<tr><td>20</td><td>
<table>
<tr><th>If the employee is</th><th>Then</th></tr>
<tr><td>MLS</td><td>• Allocate unit to the patient in Blood Order Processing
• Add ‘WELD’ and ‘LOTNO’ to the unit testing
• Enter the test results</td></tr>
<tr><td>CLT</td><td>Take unit to MLS for further processing in Sunquest</td></tr>
</table></td></tr>
</table>

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<table>
<tr><th colspan="2">Washing Components (Platelet or RBC)</th></tr>
<tr><td colspan="2">Check Prime</td></tr>
<tr><td>1</td><td>Install priming cushion</td></tr>
<tr><td>2</td><td>Replace centrifuge bowl cover</td></tr>
<tr><td>3</td><td>Ready light illuminates when powered on</td></tr>
<tr><td>4</td><td>Verify Excessive Pressure light illuminates and COBE alarms within 15 seconds</td></tr>
<tr><td colspan="2">Installing Cell Processing Set</td></tr>
<tr><td>5</td><td>Inspect cell processing set for damage, kinks, or missing caps</td></tr>
<tr><td>6</td><td>Inspect washing solution for leaks or open ports
<table>
<tr><th>If washing a</th><th>Then inspects</th></tr>
<tr><td>Platetet</td><td>Plasma-lyte</td></tr>
<tr><td>RBC</td><td>Saline</td></tr>
</table></td></tr>
<tr><td>7</td><td>Place unit number on the hexagonal seal</td></tr>
<tr><td>8</td><td>Place junction manifold
<table>
<tr><th>If washing a</th><th>Then place the Junction Manifold about 1 inch above the Red Cell Detector (RCD) and the tubing is:</th></tr>
<tr><td>Platelet</td><td>• Left outside of the RCD</td></tr>
<tr><td>RBC</td><td>• Inserted fully into the back of the slot in the RCD</td></tr>
</table></td></tr>
<tr><td>9</td><td>Place all tubing from cell processing set into the correct valve
<table>
<tr><th>Tubing</th><th>Valve</th></tr>
<tr><td>Red striped</td><td>V1</td></tr>
<tr><td>Purple striped</td><td>SOV</td></tr>
<tr><td>Green striped</td><td>2</td></tr>
<tr><td>Yellow striped</td><td>3</td></tr>
</table></td></tr>
<tr><td>10</td><td>Blue and yellow striped tubing are either clamped or heat sealed</td></tr>
<tr><td>11</td><td>Install cell processing set bag flat with spike at an angle</td></tr>
<tr><td>12</td><td>Position white alignment blocks flat side up and replace centrifuge bowl cover</td></tr>
<tr><td>13</td><td>Align rotating seal so that a point of rotating seal is pointed to the front of the machine and is at the rear of the seal weight</td></tr>
<tr><td colspan="2">Attaching Component and Washing Solution</td></tr>
<tr><td>14</td><td>Clamp hemostat on clear tubing between RCD and rotating seal</td></tr>
<tr><td>15</td><td>Use aseptic technique to remove caps from spikes and insert:
• green tubing into the washing solution
red tubing into the component</td></tr>
<tr><td>16</td><td>Record new expiration time of washed component</td></tr>
<tr><td colspan="2">Predilution and Loading of Component</td></tr>
<tr><td>17</td><td>
<table>
<tr><th>If washing a</th><th>Then set the LED program board to:</th></tr>
<tr><td>Platelet</td><td>2</td></tr>
<tr><td>RBC</td><td>1</td></tr>
</table></td></tr>
<tr><td>18</td><td>Verify controls on main control panel are in correct position and adjust if necessary
<table>
<tr><th>Component</th><th>Centrifuge Speed</th><th>Super Out Rate</th><th>Min. Agitate Time</th><th>SUPER OUT Volume</th><th>Auto/ Manual</th><th>Collect/ SOV</th></tr>
<tr><td>Platelet</td><td>3000 rpm</td><td>100 mL/min</td><td>30 sec</td><td>Platelet Vol. +50mL</td><td>Auto</td><td>SOV</td></tr>
<tr><td>RBC</td><td>3000 rpm</td><td>450 mL/min</td><td>60 sec</td><td>600 mL</td><td>Auto</td><td>SOV</td></tr>
</table></td></tr>
</table>

<table>
<tr><th colspan="2">CONTINUED - Predilution and Loading of Component</th></tr>
<tr><td>19</td><td>Allow approximately 100mls of washing solution into the component</td></tr>
<tr><td>20</td><td>Unclamp hemostat between RCD and hexagonal seal.</td></tr>
<tr><td>21</td><td>Press <BLOOD IN> and then <AIR OUT> to remove air bubbles from tubing</td></tr>
<tr><td>22</td><td>Press <BLOOD IN> and then <STOP RESET> before all the platelets drain into the hexagonal seal</td></tr>
<tr><th colspan="2">Processing and Removal of Processing Set</th></tr>
<tr><td>23</td><td>Press <START SPIN> to start wash process
<table>
<tr><th>If washing a</th><th>Then</th></tr>
<tr><td>Platelet</td><td>Change SUPER OUT volume to 400 after first cycle</td></tr>
<tr><td>RBC</td><td>Continue to next step</td></tr>
</table></td></tr>
<tr><td>24</td><td>Press <STOP RESET> when the audible alarm sounds</td></tr>
<tr><td>25</td><td>
<table>
<tr><th>If washing a</th><th>Then</th></tr>
<tr><td>Platelet</td><td>• Press PREDILUTE and then STOP to allow 50-100 mL of plasma-lyte to drain into donut
• Allow platelet to rest undisturbed for 30 minutes</td></tr>
<tr><td>RBC</td><td>Perform visual inspection of waste line for hemolysis and take necessary steps if hemolyzed</td></tr>
</table></td></tr>
<tr><td>26</td><td>Replace hemostat in clear tubing near RCD</td></tr>
<tr><td>27</td><td>Make 3 segments with tube sealer</td></tr>
<tr><td>28</td><td>Remove cell processing set from COBE disposing of waste</td></tr>
<tr><td>29</td><td>
<table>
<tr><th>If washing a</th><th>Then</th></tr>
<tr><td>Platelet</td><td>Gently massage platelet back into suspension and then allow it to rock for at least 20 minutes</td></tr>
<tr><td>RBC</td><td>Continue to next step</td></tr>
</table></td></tr>
<tr><td>30</td><td>Perform electronic processing in Sunquest</td></tr>
</table>

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<table>
<tr><th colspan="2">Preparing RBCs for Intrauterine Transfusion (IUT)</th></tr>
<tr><td>1</td><td>Use the SCD Rapidweld to add a transfer pack to the unit prior to centrifugation</td></tr>
<tr><td>2</td><td>Inspect Weld for leaks and check integrity of weld by gently pulling or squeezing tubing</td></tr>
<tr><td>3</td><td>Clamp the tubing between the product bag and transfer pack prior to centrifugation</td></tr>
<tr><td>4</td><td>Balance the centrifuge cups prior to loading the centrifuge</td></tr>
<tr><td>5</td><td>Load the product with ports up and product label facing outward</td></tr>
<tr><td>6</td><td>Select the correct program for the modification being performed and verify temperature requirements are met</td></tr>
<tr><td>7</td><td>Document centrifuge QC on the Refrigerated Centrifuge QC log</td></tr>
<tr><td>8</td><td>Remove product without disturbing the RBCs</td></tr>
<tr><td>9</td><td>Hang the RBC unit on the plasma extractor</td></tr>
<tr><td>10</td><td>Release the plasma extractor plate handle and unclamp the tubing allowing the supernatant to express into the transfer pack</td></tr>
<tr><td>11</td><td>Stop expression when the RBCs reach the top of the bag</td></tr>
<tr><td>12</td><td>Heat seal off waste bag and discard leaving sufficient tubing attached for HCT sampling</td></tr>
<tr><td>13</td><td>Strip and mix the tubing 4 times</td></tr>
<tr><td>14</td><td>Seal the stripped tubing and remove a segment for HCT verification by Hematology</td></tr>
<tr><td>15</td><td>Label test tube and submit sample for testing</td></tr>
<tr><td>16</td><td>Perform processing in Sunquest using the date and time that supernatant expression began as the process date and time</td></tr>
<tr><td>17</td><td>Perform Blood Label Check in Sunquest</td></tr>
<tr><td>18</td><td>
<table>
<tr><th>If the employee is a</th><th>Then</th></tr>
<tr><td>MLS</td><td>• Allocate unit to the patient in Blood Order Processing
• Add the WELD and LOTNO test in the unit testing
• Enter the test results</td></tr>
<tr><td>CLT</td><td>Take unit to MLS for further processing in Sunquest</td></tr>
</table>
</td></tr>
</table>

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Ortho Vision Patient Testing

1. Select a ring position into which to load samples
2. Touch <Load/Unload> and open the door
3. Load the sample rack

If loading	Then
A single rack	Proceed to next step
Multiple racks	• Select additional ring positions to load • Load sample rack

4. Close the Load Station Door

If system	**Then**
Downloads orders form the LIS	The Vision automatically scans sample ID and starts running the assay
Does not download from LIS	

If creating:	**Then:**
Order for a single sample	• Touch the sample in yellow • Touch <Create Order> • Fill in the required details • Touch <Save and Start>
Order with the same profile for multiple samples	• Touch the samples • Touch <Batch Order> • Touch <Sample ID> and select sample IDs • Fill in the required details for the assay to be run • Touch <Save and Start>

5. Touch Results menu button

If	Then
Results have been completed and sent to LIS automatically	Go to next step
Results have been flagged for review	• Retrieve card if available • Select the test result from the Results menu • Touch Show details action button • Edit gel card column grade and/or test interpretation • Accept or Reject test result as applicable • Send Accepted results to LIS

6. Open Blood Order Processing in Sunquest
7. Scan the CID of the sample to be resulted
8. Load on the 'On-line Results Available' window
9. Save all appropriate results - Click <Save>

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Ortho Vision Donor Confirmation Testing	
1	Drain segments into labeled 10X75mm tube
2	Load samples into appropriate rack with barcode labels facing out
3	Load sample rack onto the vision
4	Touch <Samples>
5	Touch <Batch Order>
6	Select samples IDs
7	Select Donor Rh Pos or Donor Rh Neg test profile as appropriate
8	Fill in the required details
9	Touch <Save and Start>
10	Open 'Blood Bank Instruments' in Sunquest
11	Select the appropriate analyzer and click ok
12	**If result is** / **Then** Not discrepant: • Check the box in the Release column for each component with acceptable results • Select "Release batch" button • Select OK Discrepant: • Do not check the box • Do not release the unit into available inventory • Clear the interface results

Ortho Vision Daily Maintenance	
1	Execute Daily Probe Maintenance and follow the on-screen prompts **If on screen prompt to maintain waste/saline/DI** / **Then** Appears: • Empty waste • Refill saline • Refill DI Water Does not appear: Continue to next step
2	Add 5 mL of 0.1 NaOH to a 10 mL vial with a supported barcode and place into position 3 of a Diluent Rack
3	Place a new 5 mL vial of 7% BSA into position 2
4	Load the Diluent Rack and follow the on-screen prompts
5	Open the maintenance door and follow the on-screen prompts
6	Clean the probe with Kimwipe moistened with 70% Isopropyl alcohol and follow the on-screen prompts
7	Close the maintenance door and follow the on-screen prompts
8	Open Load Station Door and follow the on-screen prompts
9	Remove Diluent Rack and follow the on-screen prompts
10	Close Load Station Door and follow the on-screen prompts
11	Print Maintenance History Report and Complete Ortho Vision Maintenance Log

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ABO/RH Tube Testing	
1	Label tubes per SOP Labeling Tubes
2	Add 1 drop of reagent anti-A, -B, -D and ABO/Rh control in respective labeled tubes
3	Add 2 drops of patient plasma in respective labeled tubes
4	Prepare an approximate 3-4% patient cell suspension in respective labeled tube
5	Add 1 drop of the 3-4% patient's red cell suspension in respective tubes
6	Add 1 drop of reagent A1 and B cells in respective labeled tubes
7	Mix gently and centrifuge for time posted
8	Resuspend the cell button and examine for agglutination and/or evidence of hemolysis
9	Read, grade, and record the reactions per SOP Grading Reactions in Sunquest
10	Interpret ABO/Rh correctly

Antibody Screen (PEG)	
1	Label tubes per SOP Labeling Tubes
2	Add 2 drops of patient plasma in respective labeled tubes
3	Add 1 drop of the appropriate reagent red cell in respective tubes
4	Add 2 drops of PeG in respective labeled tubes
5	Mix gently and incubates at 37°C ±1 for 10-30 minutes
6	Examine for evidence of hemolysis
7	Wash the tubes 3 times with saline
8	Add 2 drops of Anti-IgG, mixes well and centrifuges according to calibration for AHG phase testing
9	Shake gently to resuspend the cell buttons, and examine macroscopically for agglutination
10	Read, grade, and record the reaction per SOP *Grading Reactions* If the reaction is: Negative → Then: • Add 1 drop of IgG coated control cells to each tube with a negative reaction • Mix gently and centrifuge on AHG program • Shake gently to resuspend the cell button and examine for agglutination If the reaction is: Positive → Then: Continue to the next step
11	Interpret the Antibody Screen correctly

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Antibody Screen (LISS)	
1	Labels tube per SOP Labeling Tubes
2	Add 2 drops of patient plasma in respective labeled tubes
3	Add 1 drop of the appropriate reagent red cell in respective tubes
4	Add 2 drops of LISS in respective labeled tubes
5	Mix gently and incubate at 37°C ±1 for 10-30 minutes
6	Centrifuge according to calibration for LISS phase and observe for hemolysis
7	Shake gently to resuspend the cell buttons and examine macroscopically for agglutination
8	Read, grade, and record reactions per SOP Grading Reactions
9	Wash the tubes 3 times with saline
10	Add 2 drops of Anti-IgG and mix well and centrifuge according to calibration for AHG phase testing
11	Shake gently to resuspend the cell buttons and examine macroscopically for agglutination
12	Read, grade, and record the reaction per SOP *Grading Reactions* If the reaction is: Negative → • Add 1 drop of IgG coated control cells to each tube with a negative reaction • Mix gently and centrifuge on AHG program • Shake gently to resuspend the cell button and examine for agglutination If the reaction is: Positive → Continue to the next step
13	Interpret the Antibody Screen correctly

Heat Block Daily Maintenance	
1	Verify thermometer bulb is covered in saline prior to reading temperature **If the thermometer bulb is** / **Then** Covered in saline → Read the temperature Not covered in saline → • Fill with saline until the bulb is covered • Allow the temperature to equilibrate • Read the temperature
2	Read temperature, verify acceptability, and document on the Thaw Bath & Heat Block QC form.

Cell Washer Daily Maintenance	
1	Inspect tubing and drain to ensure they are: • Clear of obstructions Tubing connections are secure
2	Press and hold SALINE until the “Calibrate 56.4mL” message displays
3	Hold a graduated cylinder under the saline nozzle; press CHECK button and collect the dispensed saline
4	Verify saline volume is between 54 and 59 mL. If not, adjust volume and prime until dispensed saline volume is between 54 and 59mL
5	Clean and dry the interior
6	Document saline volume and tubing inspection on the Cell Washer & Scale QC form

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<table>
<tr><th colspan="2">DAT in Tube</th></tr>
<tr><td colspan="2">Polyspecific</td></tr>
<tr><td>1</td><td>Label tube(s) per SOP Labeling Tubes</td></tr>
<tr><td>2</td><td>Prepare an approximate 3-4% cell suspension of patient red cells</td></tr>
<tr><td>3</td><td>Add 1 drop of patient red cell suspension labeled tube</td></tr>
<tr><td>4</td><td>Wash tube(s) at least 3 times in saline</td></tr>
<tr><td>5</td><td>Add 2 drops of Anti-IgG/C3d Polyspecific AHG to the dry cell button in the tube(s)</td></tr>
<tr><td>6</td><td>Mix gently and centrifuge for time posted</td></tr>
<tr><td>7</td><td>Resuspend the cell button and examine for agglutination</td></tr>
<tr><td>8</td><td>Read, grade, and record reactions per SOP Grading Reactions
<table>
<tr><th>If DAT is</th><th>Then</th></tr>
<tr><td>Positive</td><td>Indicate IgG and C3 testing is required</td></tr>
<tr><td>Negative</td><td>• Add 1 drop of IgG coated control cells to the tube
• Mix tube(s) gently and centrifuge for time posted
• Resuspend the cell button and examine for agglutination</td></tr>
</table></td></tr>
<tr><td>9</td><td>Interpret results correctly</td></tr>
<tr><td colspan="2">IgG & C_3</td></tr>
<tr><td>14</td><td>Label 3 tubes for reagents IgG, C3 and saline control per SOP Labeling Tubes</td></tr>
<tr><td>15</td><td>Prepare an approximate 3-4% cell suspension of patient red cells</td></tr>
<tr><td>16</td><td>Add 1 drop of patient red cell suspension to appropriately labeled tube(s)</td></tr>
<tr><td>17</td><td>Wash tube(s) at least 3 times in saline</td></tr>
<tr><td>18</td><td>Add 2 drops of appropriate reagents or saline to the dry cell button in each tube</td></tr>
<tr><td>19</td><td>Mix Anti-IgG and saline control tubes gently and centrifuges for time posted</td></tr>
<tr><td>20</td><td>Read, grade, and record the reactions per SOP Grading Reactions</td></tr>
<tr><td>21</td><td>Incubate Anti-C3 tube for 5 minutes</td></tr>
<tr><td>22</td><td>Centrifuge Anti-C3 tube for time posted</td></tr>
<tr><td>23</td><td>Resuspend the cell button and examine for agglutination</td></tr>
<tr><td>24</td><td>Read, grade, and record the reactions per SOP Grading Reactions
<table>
<tr><th>If Interpretation is</th><th>Then</th></tr>
<tr><td>Positive</td><td>No further action</td></tr>
<tr><td>Negative</td><td>• Add 1 drop of the appropriate control cells to the tube
• Mix tube(s) gently and centrifuge for time posted
• Resuspend the cell button and examine for agglutination</td></tr>
</table></td></tr>
<tr><td>25</td><td>Interpret IgG and C3 AHG correctly</td></tr>
</table>

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Electronic Crossmatch	
1	Open the patient order in Blood Order Processing module
2	Select the appropriate crossmatch eligible battery
3	Review patient history and document in Sunquest if not previously completed
4	Select and allocate the appropriate red cell component that meets all special requirements
5	Click save
6	Review the “Electronic Crossmatch Eligibility Report” Click OK or Cancel, as appropriate
7	Click the button in the “Call BPI” pop up box to issue or not

Immediate Spin Crossmatch	
1	Label tubes for each crossmatch to be tested per SOP Labeling Tubes
2	Prepare an approximate 3-4% cell suspension for each donor cell to be tested
3	Add 2 drops of patient plasma/serum to tubes labeled for each donor cell
4	Add 1 drop of 3-4% donor cells to labeled tubes
5	Mix gently and centrifuge for time specified
6	Read, grade, and record results, per SOP Grading Reactions

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<table>
<tr><th colspan="2">AHG Crossmatch (PEG or LISS)</th></tr>
<tr><td>1</td><td>Label tubes for each crossmatch to be tested per SOP Labeling for Manual Testing</td></tr>
<tr><td>2</td><td>Prepare an approximate 3-4% cell suspension for each donor cell to be tested</td></tr>
<tr><td>3</td><td>Add 2 drops of patient plasma/serum to tubes labeled for each donor cell</td></tr>
<tr><td>4</td><td>Add 1 drop of 3-4% donor cells to labeled tubes</td></tr>
<tr><td>5</td><td>Mix gently and centrifuge for time specified</td></tr>
<tr><td>6</td><td>Read, grade, and record results per SOP Grading Reactions and enters results in Sunquest</td></tr>
<tr><td>7</td><td><table><tr><th>If using:</th><th>Then</th></tr><tr><td>PeG</td><td>Add 2 drops of PeG to each test tube</td></tr><tr><td>LISS</td><td>Add 2 drops of LISS to each test tube</td></tr></table></td></tr>
<tr><td>8</td><td>Mix well and incubate at 37 ±1 for 10-30 minutes</td></tr>
<tr><td>9</td><td><table><tr><th>If using:</th><th>Then</th></tr><tr><td>PeG</td><td>• Examine for evidence of hemolysis
• Continue to next step</td></tr><tr><td>LISS</td><td>• Centrifuge according to calibration for LISS phase and observe for hemolysis
• Shake gently to resuspend the cell buttons and examine macroscopically for agglutination
• Read, grade and record reactions per SOP Grading Reactions</td></tr></table></td></tr>
<tr><td>10</td><td>Wash the tubes 3 times with saline</td></tr>
<tr><td>11</td><td>Add 2 drops of Anti-IgG, mix well and centrifuge according to calibration for AHG phase testing</td></tr>
<tr><td>12</td><td>Shake gently to resuspend the cell buttons, and examine macroscopically for agglutination</td></tr>
<tr><td>13</td><td>Read, grades, and record the reactions per SOP Grading Reactions<table><tr><th>If the reaction is</th><th>Then</th></tr><tr><td>Negative</td><td>• Add 1 drop of IgG coated control cells to each tube with a negative antiglobulin test
• Mix gently and centrifuge according to calibration for AHG phase testing
• Shake gently to resuspend the cell button and examine for agglutination</td></tr><tr><td>Positive</td><td>Continue to the next step</td></tr></table></td></tr>
<tr><td>14</td><td>Interpret the AHG crossmatch correctly</td></tr>
</table>

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<table>
<tr><th colspan="2">Antigen Typing</th></tr>
<tr><td>1</td><td>Label tube(s) per SOP Labeling Tubes including saline/albumin controls and QC if required</td></tr>
<tr><td>2</td><td>Prepare an approximate 3-4% cell suspension of patient/donor red cells to be tested</td></tr>
<tr><td>3</td><td>Add the appropriate number of drops of antisera to labeled tubes as indicated by the manufacturer’s package insert (or Instructions for Use)</td></tr>
<tr><td>4</td><td>Add 1 drop of 3-4% cell suspension to labeled tubes</td></tr>
<tr><td>5</td><td>Mix well and incubate at appropriate temperature and time for antisera as indicated by the manufacturer’s package insert (or Instructions for Use)</td></tr>
<tr><td>6</td><td>
<table>
<tr><th>If required phase of testing is</th><th>Then</th></tr>
<tr><td>Not AHG</td><td>Centrifuge using saline program</td></tr>
<tr><td>AHG</td><td>• Wash as indicated by the manufacturer’s package insert (or Instructions for Use)
• Add 2 drops of Anti-IgG and centrifuge using AHG program</td></tr>
</table>
</td></tr>
<tr><td>7</td><td>Shake gently to resuspend the cell button, and examine macroscopically for agglutination</td></tr>
<tr><td>8</td><td>Read and grade per SOP Grading Reactions, and record on Phenotyping Worksheet and in Sunquest if applicable
<table>
<tr><th>If required phase of testing is</th><th>Then</th></tr>
<tr><td>NOT AHG</td><td>No further action is required</td></tr>
<tr><td>AHG</td><td>• Add 1 drop of IgG coated control cells to each tube with a negative agglutination test
• Mix gently and centrifuge using the AHG program
• Shake gently to resuspend the cell button, and examine macroscopically for agglutination</td></tr>
</table>
</td></tr>
</table>

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Fetal Maternal hemorrhage RapidScreen	
1	Label tubes per SOP Labeling Tubes
2	Make an approximate 3-4% red cell suspension of well-mixed maternal blood in a properly labeled tube
3	Place one drop of the anti-D reagent from the kit in properly labeled tubes for patient and controls
4	Add one drop of the maternal red blood cell suspension to patient tube
5	Add one drop of each well mixed control to the appropriate tubes
6	Mix well and incubate for 5 minutes at room temperature (18-30°C)
7	Wash test tubes 4 times with blood bank saline
8	Add one drop of well-mixed Indicator Cells from the kit and mix gently
9	Centrifuge for time specified
10	Re-suspend red blood cell button completely and examine 5 fields on low-power (10X) microscopically for mixed field agglutination. This can be done in the tube or by transferring the contents of the test tubes onto a microscope slide. Counting should be performed from the slide only.
11	Read and grade the negative and positive controls with the specimen, per SOP *Grading Reactions*
12	Interpret FMH RapidScreen reactions correctly

SickleDex Hemoglobin S	
1	Label 12 x 75 mm tubes for each donor to be tested, one positive control, and one negative control per SOP Labeling Tubes
2	Place tubes in testing rack and fill each tube with working SickleDex Solubility Buffer to the red line on rack (approximately 2 mL)
3	Return working buffer to refrigerator immediately after use
4	Bring controls and buffer to room temperature (18°C to 30°C) for at least 10 minutes before use
5	Mix controls by holding vertically between hands and rolling the vials back and forth for 20-30 seconds followed by inverting end over-end 20 times
6	Add 1 drop of each control into the appropriately labeled control tube by inverting the control and holding it vertically directly over the test tube for accurate delivery. Wipe threads on each control, if necessary
7	Add 20µL of whole blood or 10µL of packed red blood cells to each tube
8	Mix contents of test tubes
9	Allow tubes to stand at room temperature for at least 6 minutes, no longer than 60 minutes
10	Read reaction macroscopically by looking through the test tubes at black lines on the back of the testing rack
11	Interpret Sickle Cell Screening test results correctly
12	Record results in Sunquest or manual form

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Testing with DTT Treated Cells	
1	Label tubes for each reagent cell
2	Add DTT-treated reagent cells in Alsever's solution to tube
3	Centrifuge for 1 minute
4	Decant supernatant
5	Make a 3-4% cell suspension using saline
6	Perform daily reagent QC prior to patient testing

EGA Testing	
1	Label test tubes per SOP Labeling Tubes
2	Wash patient red cells 3 times with blood bank saline, making a 3-4% cell suspension after final wash
3	Place 30 drops of the 3-4% cell suspension in a labeled tube
4	Centrifuge washed red cells to form a cell button and remove supernatant
5	Prepare EDTA glycine by adding 16 drops of Solution 2 into a labeled tube and then 4 drops of Solution 1
6	Add the combined EGA solutions to the packed washed cells and mix gently
7	Incubate for 2 minutes at Room Temperature
8	Add 4 drops of Solution 3, mix well, and centrifuge for 30 sec
9	Remove and discard the supernatant, add saline to treated cells
10	Wash red cells 3 times with blood bank saline
11	Perform DAT on treated cells If DAT is: Positive → Then: • Repeat treatment starting at step 3 • At step 7 incubates for 1.5 minutes If DAT is: Negative → Then: Proceed to antigen typing

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Eluate Testing	
1	Label tubes per SOP Labeling Tubes
2	Centrifuge patient specimen and remove most, if not all of the plasma, if necessary
3	Place an aliquot of patient red blood cells (a smaller volume is acceptable if specimen sample is insufficient) in a labeled tube and wash it once with saline.
4	Wash the aliquot four times with Working Wash Solution packing the fourth wash for at least two minutes
5	Remove supernatant and save the last wash in a labeled tube
6	Add 20 drops of washed red blood cells to a clean labeled tube (a smaller volume is acceptable if specimen sample is insufficient)
7	Add 20 drops of Eluting Solution to the washed red blood cells (use equal drops of Eluting Solution if the patient cells fall short of 20 drops) invert 4 times to mix.
8	Centrifuge promptly for 45-60 seconds
9	Transfer supernatant eluate into clean labeled tube, discard the treated red blood cells
10	Add Buffering Solution until it turns pale blue
11	Mix well and, if necessary, centrifuge for 30 seconds, transfer eluate to a clean labeled tube (eluate must be clear of any precipitate or cellular debris)

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