Preparing Rejuvenated Red Blood Cells

Refer to the current Instructions For Use.

Purpose
To describe the procedure for preparing rejuvenated Red Blood Cells using rejuvesol™ Red Blood Cell Processing Solution.

What You Need
- CPD/AS-1 or CP2D/AS-3 Leukoreduced Red Blood Cells (LRBC)
- rejuvesol Solution (one vial per unit LRBC)
- Y-type Rejuvenation set (one set per unit LRBC)
- Sterile Alcohol swabs
- Sterile tubing connection device (STCD)
- Plastic zip top bags
- Weights
- Timer
- Incubation Unit – Water Bath or equivalent device maintained at 37 °C.

Forms/Job Aids/CATs/ Samples
- rejuvesol Solution Instructions For Use
- Rejuvenated Red Blood Cell Worksheet for Immediate Use
- Rejuvenated Red Blood Cell Worksheet for Cyropreserved Units

Steps to Follow - Rejuvenation

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
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</thead>
</table>
| 1    | • Collect a 3 mL sample of the LRBC.  
     | • After sampling, measure and document the gross weight, tare weight, and calculate the net weight of the LRBC on the applicable Rejuvenated Red Blood Cell Worksheet. (Immediate Use or Cyropreservation) |
| 2    | • Remove the protective flip-off cap from the vial of rejuvesol Solution and cleanse the rubber stopper with an alcohol swab.  
     | • While allowing the alcohol to dry, remove the Y-type rejuvenation set from the package and prepare it for use:  
     | o Close the sliding clamps.  
     | o Seal and detach the empty bag from the tubing. |
### Steps to Follow - Rejuvenation

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<td>3</td>
<td>Once the alcohol is completely dried, use aseptic technique and insert the vented spike from the tubing set into the rubber stopper of the rejuvenesol Solution vial.</td>
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<td>4</td>
<td>Close the green tab on the drip chamber until it clicks, then open it again.</td>
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<td>5</td>
<td>Using the STCD, connect the LRBC with the Y-type rejuvenation set. Document the time on the applicable Rejuvenated Red Blood Cell Worksheet.</td>
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<td>6</td>
<td>Invert and elevate the rejuvenesol vial and squeeze the drip chamber to prime the system.</td>
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<td>7</td>
<td>Open the slide clamp of the Y-type rejuvenation set and allow the entire contents of the vial to flow into the LRBC bag. Gently mix the LRBC bag until all of the solution is added.</td>
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<td>8</td>
<td>Close the slide clamp, seal and detach the tubing to the rejuvenesol Solution container, and discard the container and tubing in the non-biohazard trash.</td>
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<tr>
<td>9</td>
<td>Document the water bath thermometer ID on the applicable Rejuvenated Red Blood Cell Worksheet. Ensure that the water bath is at the proper temperature.</td>
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</table>
| 10   | If using a water bath, prepare for incubation by placing the LRBC mixture in two zip-top bags.  
• Expel out as much air as possible from the first bag before sealing.  
• Add weights to the outer bag before sealing, and remove as much air as possible before sealing. If desired, bagged weights may be placed on top of the submerged unit.  
• Use packaging tape to seal the outer bag closed if required.  
• Note: If using an alternative thermal transfer device, ensure that the device is operating in the desired temperature range and follow the manufacturer’s instructions for use. |
| 11   | Place the prepared unit in the thermal transfer device and start a 60-minute timer. During the incubation ensure the unit is agitated without removing it from the fixed temperature environment. |

### What’s Next

When the timer sounds, remove the LRBC bag from the thermal transfer device and remove the rejuvenated LRBC unit from the zip-top bags, if used. Then, perform the process that applies for the intended use of the rejuvenated LRBCs:

<table>
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<tr>
<th>Intended Use</th>
<th>Process</th>
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<tr>
<td><strong>Immediate Transfusion – Post Wash</strong></td>
<td>Washed Red Blood Cells*</td>
</tr>
<tr>
<td><strong>Cryopreservation/Freezing</strong></td>
<td>Preparing Frozen Red Blood Cells*</td>
</tr>
</tbody>
</table>

* Per center SOP.
For Immediate Transfusion – Post Wash

Upon completion of the wash process:

- Weigh the rejuvenated, washed LRBC. Measure and document the gross weight, tare weight and calculate the net weights on the Rejuvenated Red Blood Cell Worksheet for Immediate Transfusion.
- Collect a 3 mL sample of the rejuvenated and washed LRBC after determining the gross and net weights.

For Cryopreserved Cells:

Upon completion of the thawing process:

- Collect a 3 mL sample of the thawed, rejuvenated LRBC before determining the gross and net weights of the thawed unit.
- Then measure and document the gross weight, tare weight and calculate the net weights of the thawed unit on the Rejuvenated Red Blood Cell Worksheet for Cyropreserved Units.
- After deglycerolization, weigh the deglycerolized unit. Measure and document the gross weight, tare weight and calculate the net weights of the deglycerolized unit on the Rejuvenated Red Blood Cell Worksheet for Cyropreserved Units.
- Collect a 3 mL sample after determining the gross and net weights of the deglycerolized cells.

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