NOTE: REJUVENATED RBC STORED IN ANY OTHER ANTICOAGULANT/ADDITIVE SOLUTION COMBINATION HAVE NOT BEEN APPROVED FOR CRYOPRESERVATION.

MATERIALS AND EQUIPMENT
(As Suggested or Equivalent)

- Temperature-controlled (cooling/warming) bath (Bio-Rad B-80, or equivalent)
- 100 mm Hg glass barometer
- 1,1,1,1,2,3,3,3-Octafluoropropane gas (C3F8)
- Y-type Rejuvenation Set for the addition of rejuvesol® Solution (Citra PN 7212) or equivalent
- Squeeze tubing (26Fr, 20Fr, 18Fr, 16Fr)
- Overwrapped unit from Water Bath
- Primary collection bag
- Rejuvesol® Solution (Citra PN 7012) vial
- Primary collection bag

III. TO PROCESS THE RED BLOOD CELL/SOLUTION MIXTURE FOR 60 MINUTES AT 37 °C

1. Place the primary collection bag containing the red blood cell/Solution mixture with the attached transfer bag of the Y-type Rejuvenation Set that connects the primary collection bag and the various tubing to the system for reverse air priming to
2. Set the slide clamps following the open slide clamp of the Y-type Rejuvenation Set.
3. Place the slide clamps open to prime the system and open the slide clamp of the primary collection bag.
4. Place the primary collection bag and vial approximately 28 inches above the water bath with waterproof tape.
5. Incubate the unit in a 37 °C water bath for 60 minutes with agitation.
6. Remove the overwrapped unit from the water bath; dry the outer overwrap lead weights (to keep the unit submerged during incubation); flatten and seal.
7. Allow the entire contents of the vial to cool down to room temperature.
8. After all of the contents are transferred, close the slide clamp in the Y-type Rejuvenation Set.
10. Proceed immediately to Section II.

REFERENCES

Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

Immediate after rejuvenation, RBC must either be washed via an approved protocol prior to transfusion or frozen. RBC rejuvenated at 42 days of liquid storage, washed, and stored for up to 28 days must be frozen to a hematocrit of 5 % after glycerolization per Standard Operating Procedure. Each 50 mL of RBC collected in CPD or CPDA-1 cannot be rejuvesol® Solution vial. The rejuvesol® Solution must not be added to whole blood or primary collection bags. The rejuvesol® Solution has been transferred, close the clamp and overwrap the red blood cell/bag with clean, disposable toweling and carefully remove the plastic overwrap and heat seal the tubing three times between the portion of the Y-type Rejuvenation Set to the integral tubing of the blood warmer. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

NOTE: Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

Maximum weekly RBC unit volume processed is 36,000 mL or the volume as stated in the package insert for the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

Rejuvenation of prior red blood cells processed with rejuvesol® Solution is due process. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

See the package insert for more information on rejuvesol® Solution for rejuvenation. A combination of 10% dimethylsulfoxide (DMSO) and 90% autologous plasma must be used. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

Procedure

1. Remove the flip-off protective cap from the rejuvesol® Solution vial. See the package insert for more information on rejuvesol® Solution for rejuvenation. A combination of 10% dimethylsulfoxide (DMSO) and 90% autologous plasma must be used. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

2. Seal the plastic overwrap bag with tape or heat seal. Centrifugation after rejuvenation is not required for RBC intended to be frozen. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

3. Place the primary collection bag containing the rejuvenated red blood cells into a saline water bath at 37 °C. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

4. The primary collection bag must then be added to an approved cell washing system. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

5. Once the primary collection bag containing the rejuvenated red blood cells (CPDA-1) has been added to the approved cell washing system, proceed with the usual protocol for the approved washing system. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

6. If a drip chamber is on the tubing set, squeeze the drip chamber to prime the tubing set, open the clamp and aseptically insert a filtered airway needle through the vented spike remains attached to the adaptor port. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

7. Allow the entire contents of the rejuvesol® Solution mixture into a plastic overwrap bag with the unused portion of the rejuvesol® Solution in the rejuvesol® Solution bag. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

8. Overwrap bag impulse sealer (Stericon 210X). Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

9. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.

10. Rejuvenated-glycerolized RBC to be frozen in the 800 mL primary collection bag. Rejuvenation is currently only allowed for red blood cell concentrates (RBC) that have not been washed and stored for 42 days (CP2D/AS-3, leukocyte reduced) or for 11/34 in Site B) the concentration of 2,3-DPG reached at least 80% of the day 0 value.


WARNINGs AND CAUTIONs

NOTES:

- The final concentration of ATP and 2,3-DPG achieved was 0.550 g, inosine 1.34 g, adenine 0.034 g, dibasic sodium phosphate (heptahydrate) 0.730 g, and monobasic sodium phosphate 0.260 g.

- After 6 days of storage may achieve 2,3-DPG levels in excess of 2 times normal and ATP levels in excess of 4 times normal.

- Rejuvenation of CPD or CPDA-1 RBC for Immediate use
- Rejuvenation of CPD/AS-1 RBC for Upcoming surgery
- Rejuvenation of CP2D/AS-3, leukocyte reduced) are referred to hereafter as CPD, CPDA-1, CPD/AS-1, and CP2D/AS-3, leukocyte reduced.
- CP2D/AS-3, leukocyte reduced) are determined at a reference value of 90% for each compound.
- InSite B at 24 days or CPDA-1 RBC at 38 days, the concentrations of 2,3-DPG and ATP increases to above normal.

- An in vitro loss of red blood cells occurs with CP2D/AS-3, leukocyte reduced) are determined at a reference value of 90% for each compound.
- InSite B at 24 days or CPDA-1 RBC at 38 days, the concentrations of 2,3-DPG and ATP increases to above normal.

- Table of compounds determined at a reference value of 90% for each compound.
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- Rejuvenation of CPD/AS-1 RBC for Upcoming surgery
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- CP2D/AS-3, leukocyte reduced) are determined at a reference value of 90% for each compound.
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