

XIII. Appendix A

Rehydration Instructions for StablePlate RX™

1. MATERIALS AND EQUIPMENT

- 4.1.1 Sterile 10-12ml syringes
- 4.1.2 Sterile sterile water for injection (WFI) for injection quality
- 4.1.3 Sterile 18 gauge needles
- 4.1.4 Stable Plate RX™

2. SAFETY

- 2.1 CAUTION: Canine derived blood products are used in this procedure. Standard BSL-2 protocols must be followed. In case of accidental exposure, follow necessary decontamination procedures, taking advantage of eye wash stations and/or showers as necessary.

3. DEFINITIONS AND ABBREVIATIONS

- 3.1 RT = Room temperature, standard RT is 18-24°C
- 3.2 PPE = Personal protective equipment, usually refers to (at minimum) lab gloves, lab coats, and proper attire.
- 3.3 BSL-2 = Biosafety level 2. A level of biosafety considered appropriate for agents that can cause human disease, but whose potential for transmission is limited.

4. PROCEDURE

- 4.1 Put on proper PPE.
- 4.2 Remove the aluminum seal to expose rubber stopper.
- 4.3 Draw 10ml of sterile water using a sterile syringe and needle. This volume is specific to the 10ml vial fill; confirm the fill size on the vial.
- 4.4 Rehydrate the StablePlateRX™ vial with the appropriate volume of sterile WFI, directing the stream of liquid against the glass side of the vial rather than directly into the cake.
Record the start time of rehydration.
- 4.5 Gently swirl the rehydrated StablePlateRX™ vial for approximately 5-10 seconds to assist in the rehydration process.
- 4.6 Allow the rehydrated material to rest for 10 minutes at RT to allow for full rehydration before use.
- 4.7 Swirl the StablePlateRX™ every few minutes (at approximately 5 minutes) while rehydrating.
- 4.8 If clumps are observed, swirl StablePlateRX™ and let rest for another 5 minutes.

XIV. Appendix B**Thawing Instructions for DMSO Cryopreserved Platelets****1. MATERIALS AND EQUIPMENT**

- 1.1.1 37°C water bath
- 1.1.2 Stopwatch or timer
- 1.1.3 DMSO Cryopreserved platelets

2. SAFETY

- 2.1 CAUTION: Canine derived blood products and DMSO are used in this procedure. Standard BSL-2 protocols must be followed. In case of accidental exposure, follow necessary decontamination procedures, taking advantage of eye wash stations and/or showers as necessary.

3. DEFINITIONS AND ABBREVIATIONS

- 3.1 PPE = Personal protective equipment, usually refers to (at minimum) lab gloves, lab coats, and proper attire.
- 3.2 BSL-2 = Biosafety level 2. A level of biosafety considered appropriate for agents that can cause human disease, but whose potential for transmission is limited.

4. PROCEDURE

- 4.1 Put on proper PPE.
- 4.2 Carefully place the DMSO Cryopreserved platelet unit(s) for thawing in a sealable plastic bag(s).
- 4.3 Verify the temperature of the waterbath at 37°C.
- 4.4 Gently float the unit in the 37°C waterbath.
- 4.5 Start the timer or stopwatch upon entrance into the waterbath.
- 4.6 Evaluate every 10 minutes for evidence of product thaw by gently swirling package.
- 4.7 Remove from the waterbath and sealable plastic bag when product is thawed.
- 4.8 Remove from cardboard container and bubble overwrap to evaluate the product bag for breakage.
- 4.9 If clumps are observed, swirl DMSO cryopreserved platelets and let rest for another 5 minutes.
- 4.10 If clumps persist that are greater than 0.5cm in size, discard the unit and record on the appropriate form.

XV. Appendix C**ADMINISTRATION OF STABLEPLATE RX™****5. MATERIALS AND EQUIPMENT**

- 4.1.5 Appropriate sterile syringes for dosing
- 4.1.6 Syringe pump for administration (Optional)
- 4.1.7 Stable Plate RX™

6. SAFETY

- 6.1 CAUTION: Canine derived blood products are used in this procedure. Standard BSL-2 protocols must be followed. In case of accidental exposure, follow necessary decontamination procedures, taking advantage of eye wash stations and/or showers as necessary.

7. DEFINITIONS AND ABBREVIATIONS

- 7.1 RT = Room temperature, standard RT is 18-24°C
- 7.2 PPE = Personal protective equipment, usually refers to (at minimum) lab gloves, lab coats, and proper attire.
- 7.3 BSL-2 = Biosafety level 2. A level of biosafety considered appropriate for agents that can cause human disease, but whose potential for transmission is limited.
- 7.4 ml = milliliters
- 7.5 kg = kilogram

4. DOSING

- 7.6 The designated dose for canine patients is 3×10^9 /kg.
- 7.7 Each vial contains approximately 1.5×10^9 lyophilized platelets/ml.
- 7.8 One vial provides dosing for 5kg.
- 7.9 One vial provides 10 milliliters (ml) of product.
- 7.10 **Calculate dosing using the formula below:**
 - 7.10.1 **ml of StablePlateRX™ = [(weight of patient in kg) / 5kg] X 10mls**

7.11 Calculate number of vials using the formula below:

7.11.1 **no. of vials = Number of mls/ 10mls**

7.11.2 NOTE: Round to the next number if vial size is not even.

7.11.3 Partial vials cannot be reused.

8. PROCEDURE

8.1 Put on proper PPE.

8.2 Select the number of rehydrated vials to provide the calculated dose.

8.3 Rehydrate using provided instructions.

8.4 *Product must be utilized within 1 hour of rehydration.*

8.5 Confirm patency of venous access in patient by flushing with normal saline. NOTE: Catheter should be at least 20 gauge.

8.6 Draw calculated dose into the appropriate sized syringe.

8.7 Administer through standard extension set or injection port at 1ml/min. NOTE: A syringe pump may be utilized for administration.

8.8 NOTE TIME POINT AT THE END OF ADMINISTRATION!

8.9 Flush extension set with an appropriate amount of saline after completing the infusion.

8.10 Monitor for transfusion and/or anaphylactic response.

8.11 Collect 1 hour timepoint data when appropriate.

XVII. Appendix D

ADMINISTRATION OF DMSO CRYOPRESERVED PLATELETS

9. MATERIALS AND EQUIPMENT

- 4.1.8 Standard In Line Blood Filter
- 4.1.9 DMSO cryopreserved platelet unit(s)

10. SAFETY

- 10.1 CAUTION: Canine derived blood products are used in this procedure. Standard BSL-2 protocols must be followed. In case of accidental exposure, follow necessary decontamination procedures, taking advantage of eye wash stations and/or showers as necessary. This product contains 6% DMSO, a known carcinogen.

11. DEFINITIONS AND ABBREVIATIONS

- 11.1 PPE = Personal protective equipment, usually refers to (at minimum) lab gloves, lab coats, and proper attire.
- 11.2 BSL-2 = Biosafety level 2. A level of biosafety considered appropriate for agents that can cause human disease, but whose potential for transmission is limited.
- 11.3 ml = milliliters
- 11.4 kg = kilogram

4. DOSING

- 11.5 The designated dose for canine patients is $3 \times 10^9/\text{kg}$.
- 11.6 Each unit contains approximately 1.5×10^{10} platelets.
- 11.7 One unit provides dosing for 5kg.
- 11.8 One unit provides 20 to 100 milliliters (ml) of product.
- 11.9 **Calculate dosing using the formula below:**
 - 11.9.1 **No. of platelets = (Weight of the dog in kg)(3.0×10^9)**
- 11.10 **Calculate number of units using the formula below:**
 - 11.10.1 **no. of units = No. of platelets/ 1.5×10^{10}**
 - 11.10.2 NOTE: Round to the next number if unit size is not even.

11.10.3 Partial units cannot be reused.

12. PROCEDURE

- 12.1 Put on proper PPE.
- 12.2 Select the number of units to provide the calculated dose
- 12.3 Warm unit(s) according to instructions in Appendix B.
- 12.4 *Product must be utilized within 1 hour of warming.*
- 12.5 Confirm patency of venous access in patient by flushing with normal saline. NOTE: Catheter should be at least 20 gauge.
- 12.6 Using aseptic technique, attach an in-line blood filter to allow administration by gravity flow.
- 12.7 Administer through standard extension set or injection port at 1ml/min. NOTE: A pump is NOT allowed for administration.
- 12.8 NOTE TIME POINT AT THE END OF ADMINISTRATION!
- 12.9 Flush extension set with an appropriate amount of saline after completing the infusion.
- 12.10 Monitor for transfusion and/or anaphylactic response.
- 12.11 Collect 1 hour timepoint data when appropriate.