ALBERTA PRECISION LABORATORIES
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Gammagard® S/D Reconstitution Instructions

Applicability

This document applies to APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.

Supplies Required

Use only the provided sterile water for injection (diluent) provided with the product for reconstituting the product. The vial adapter must be used for reconstitution to ensure the product is filtered.

Contained in Box:
- Gammagard® S/D lyophilized concentrate
- Sterile Water for Injection (diluent)

If preparing a 10% solution:
- Sterile needle
- Sterile syringe, large enough to contain discarded diluent

Aseptic technique must be used at all times

Instructions:

*Note: Reconstitute immediately before use

**Note: The full volume of diluent provided will result in a 5% solution of IVIG. If a 10% solution is required, half the volume of diluent will need to be removed and discarded. (described in step 5)

1. If refrigerated, warm both the unopened product vial and sterile water for injection to room temperature.

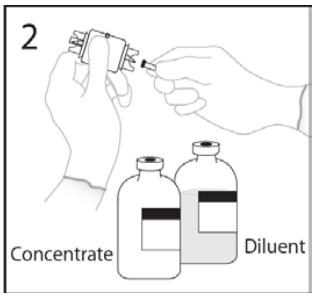
2. Remove caps from concentrate and diluent vials to expose central portion of rubber stoppers.

3. Cleanse stoppers with germicidal solution and allow to dry.

4. To prepare a 5% solution: proceed to step 6.

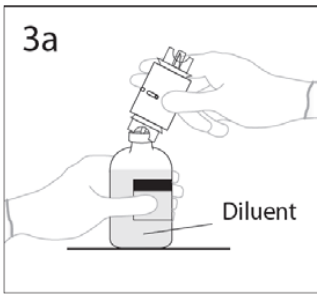
5. To prepare a 10% solution in a 5g vial:
   a) Using aseptic technique, withdraw the 48 mL of diluent using a sterile hypodermic needle and syringe.
   b) Discard the filled syringe into a suitable puncture proof container.
   c) Using the remaining diluent, proceed to Step 6.

6. Remove the spike cap from one end of transfer device. Do not touch the spike.

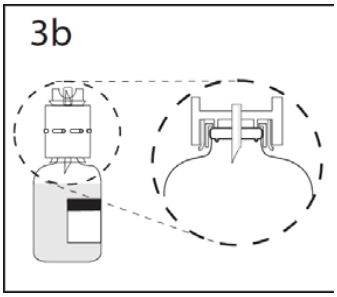


7. Place the diluent vial on a flat surface. Use the exposed end of the transfer device to spike the diluent vial through the centre of the stopper.

   Caution: Failure to insert the spike into the centre of the stopper may result in dislodging of the stopper

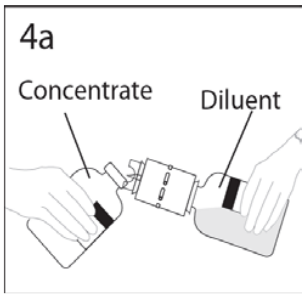


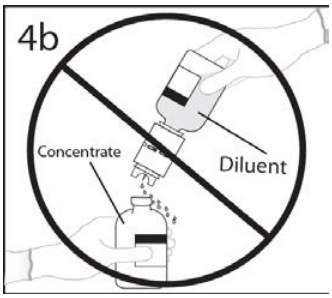
8. Ensure the collar collapses fully into the device by pushing down on the transfer device firmly. While holding onto the transfer device, remove the remaining spike cover. Do not touch the spike.



9. Hold the diluent vial with the attached transfer device at an angle to the concentrate vial to prevent spilling the diluent.

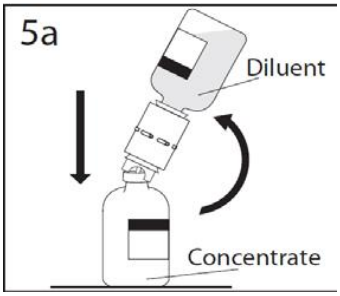
   Note: **Do not** hold the diluent vial upside down. This can lead to diluent spillage.



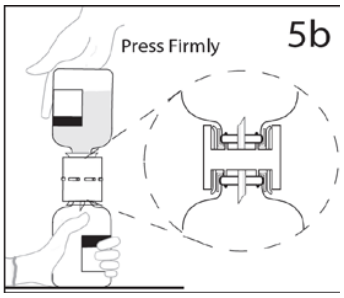


10. Spike the concentrate vial through the centre of the stopper while quickly inverting the diluent vial to minimize spilling out the diluent.

    Caution: Failure to insert the spike into the centre of the stopper may result in dislodging of the stopper and loss of vacuum.



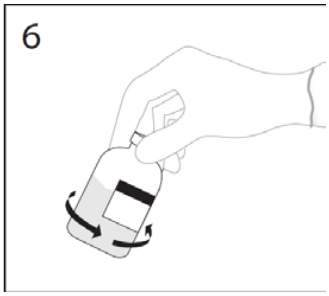
11. Ensure the stopper collapses fully into the device by pushing down firmly on the diluent vial.



12. After transfer of diluent is complete, remove the transfer device and empty the diluent vial. Immediately and gently swirl the concentrate vial to thoroughly mix the contents.

    Discard the transfer device.

    Caution: Do not shake. Avoid foaming.



13. Label the vial per AHS Transfusion of Blood Components Policy & Procedure

Troubleshooting:

- If vacuum is lost, use a sterile non-filtered blunt needle and syringe to withdraw remaining diluent from the vial and transfer to lyophilized product vial.

Contact Information

For questions or comments about this document, please contact
Transfusion.SafetyTeam@albertaprecisionlabs.ca

References

Gammagard S/D® Product Monograph. Available at www.takeda.com