

INSTRUCTIONS FOR RETURNING FENWAL PRODUCTS FOR EVALUATION

These instructions are applicable to ALYX®, AMICUS®, AUTOPHERESIS-C®, and Whole Blood products.

- ✓ Please use universal precautions when packaging disposable products.
- ✓ For the safety of everyone, samples that are not properly decontaminated and packaged will not be evaluated.
- ✓ Samples that are known or suspected to be positive for any infectious disease CANNOT be returned!

Supplies Needed For Product Returns

- 1 shipping box
- 5 preprinted Commercial Invoices
- 1 Domestic or International Airway Bill
- 1 Evaluation Sample Sticker
- 2 Absorbent Pads
- 1 biohazard styrofoam container (needle return only)
- 2 biohazard plastic (red or clear) bags

Sample Packaging Instructions

1. Complete and fax the performance report to Fenwal Post Market Quality Assurance (toll free **888-858-2983**).
2. If the sample has been in contact with blood or bodily fluids, wipe the exterior and all contaminated surfaces of the sample with a 10 % bleach solution or an equivalent alternative.
 - If the sample has not been in contact with blood or body fluids, disregard step 2 and proceed with step 3.
3. Remove all needles (unless the report is regarding the needle).
 - If the report is regarding a needle, engage needle guard over the needle.
4. All tubing that would allow blood or fluid to leak from the kit must be hermetically sealed.
5. Place the sample inside one of the biohazard bags (or the biohazard labeled Styrofoam container for needle returns).
6. Place the sample and one absorbent pad in the bag and seal the bag.
7. Place the second absorbent pad and the bagged sample (from step 6) into the second biohazard bag sealing the second bag.
8. Place the now double bagged sample inside the shipping container.
9. Include a copy of the applicable Performance Report **inside** the shipping container **outside** the biohazard bag containing the sample.
10. Affix the Evaluation Sample sticker to the outside of the shipping container.
11. Sign and date the bottom of the airway bill.
12. Attach the airway bill to the shipping carton.
13. Sign and date all commercial invoices (if they were provided). Insert the signed copies into the mailing pouch.

If you have any questions please contact Fenwal Post Market Quality Assurance Team toll free at **800-933-6925**.