

ALYX System Kit Performance Report



Important: If reaction or injury has occurred call Fresenius Kabi Post-Market Quality Assurance at 1-800-933-6925.

Incident Date: _____ Instrument S/N: _____ Software Version: _____ UDI No.: _____
 Product Code: _____ Lot No.: _____ Product Collected: _____ mL
 Red Cell Container Label Identifier (Lower right corner - A or B): _____

When Was the Problem Detected?

- Set Up Draw Cycle # _____ All, Final Filtration / Processing Product Unloading Kit
 Prime _____ % Return Cycle # _____ All, Final Weighing Product

Problem Type (Mark all applicable)

- Blood Leak Separated Solution Leak Alarms? Yes No Alarm Code: _____
 Kink Broken Restriction / No Flow Other _____

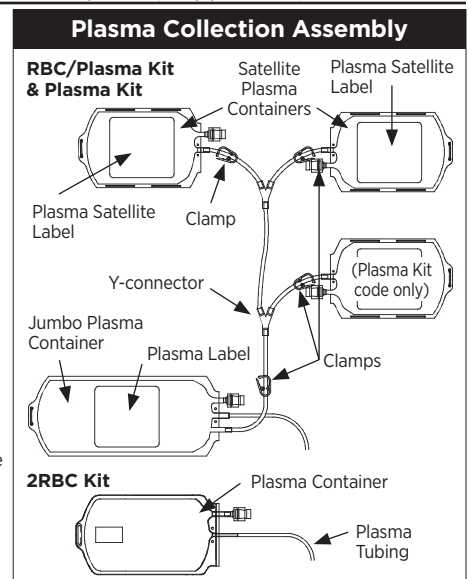
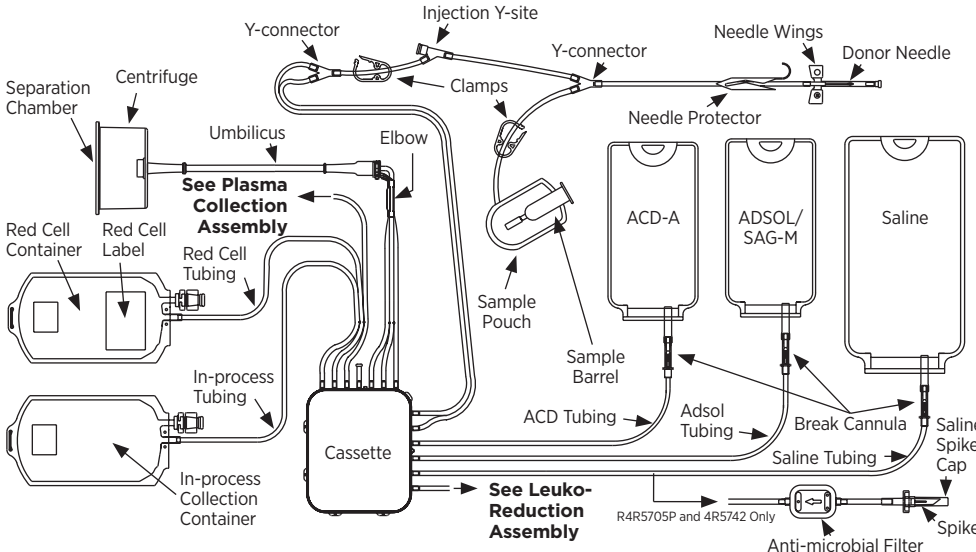
Please answer the following questions:

1. Was there any adverse event or injury? Yes No
2. Was the procedure successfully completed? Yes No N/A
3. If no, was the procedure stopped due to a soft goods incident? Yes No N/A
4. Was product lost? Yes No N/A

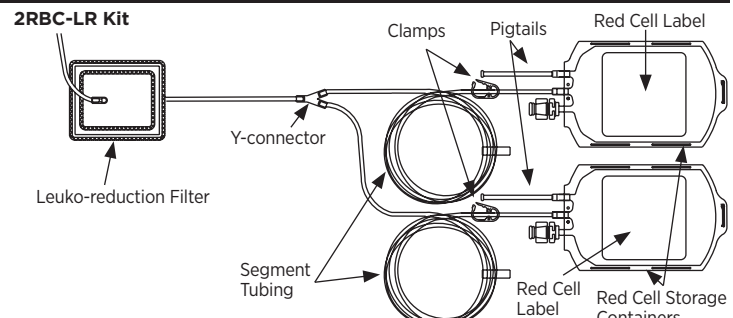
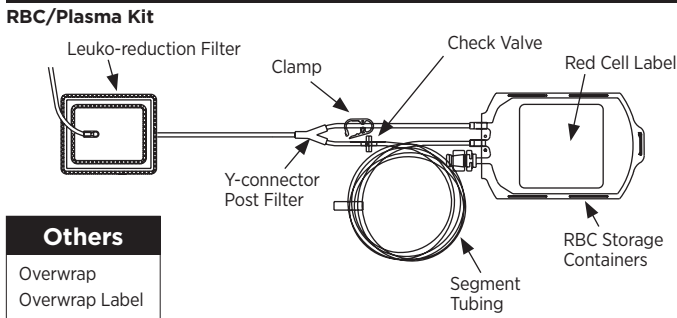
Check box if you do **NOT** wish to receive response letters.

E-mail address for letter recipient (if applicable) _____

Please circle specific components on the diagram where incident occurred



Leuko-Reduction Assembly



- Others**
 Overwrap
 Overwrap Label

Additional Problem Description / Explanation

Kit Return To Fresenius Kabi

1. Sample available for evaluation? Yes No Not Required
 2. Sample return box needed? Yes No Return label only
 3. Picture available for evaluation? Yes No
- Please e-mail a clear picture **along with this report** to **mdpmqa.usa@fresenius-kabi.com**

Center Authorized Signature/Date: _____

Customer Information (please print)

The following information is required to receive a credit

Facility Name: _____
 Contact Person: _____
 Account Number (if known): _____
 Operator Name: _____
 Street Address: _____
 City/State/Zip: _____
 Phone Number: _____
 Contact Person's E-mail: _____

Fax this report to 1-888-858-2983 or E-mail to mdpmqa.usa@fresenius-kabi.com and include a copy of this form when returning a kit.