

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

ALYX™ System Kit Performance Report

Complete these three questions if issue occurred during a donation.
 Was there any injury / adverse donor reaction? Yes No
 Was the donation successfully completed? Yes No
 If No, was the donation stopped due to a soft goods incident? Yes No

Incident Date: _____ Instrument Serial Number: _____
 Product Code: _____ Lot Number: _____

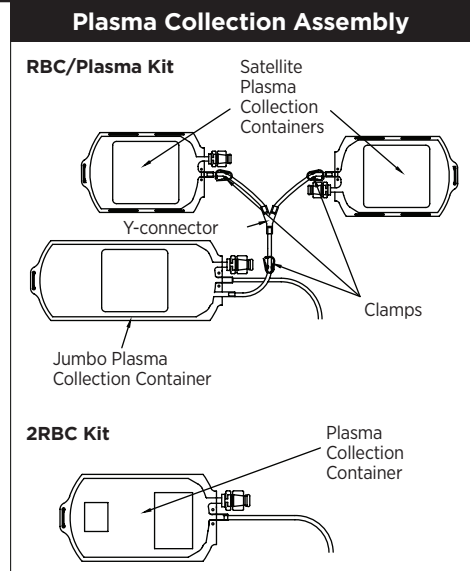
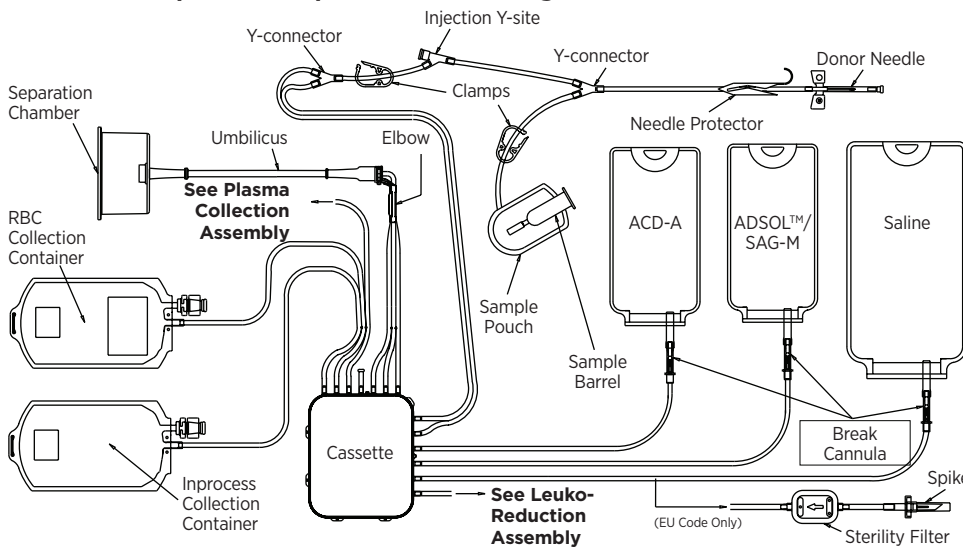
When Was The Problem Detected

Set Up Draw Cycle # _____ All, Final Filtration / Processing Product Unloading Kit
 Prime Return Cycle # _____ All, Final Weighing Product Product Collected: _____ mL

Problem Type (Mark all applicable)

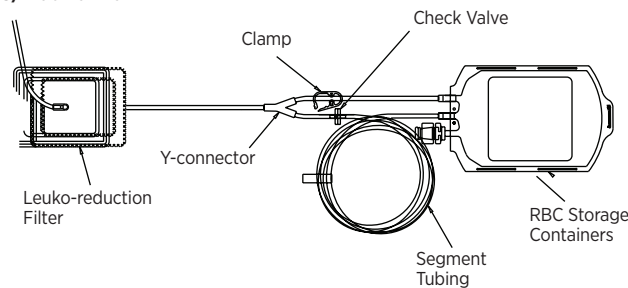
Blood Leak Separated Solution Leak Alarms (Specify) _____
 Kink Broken Restriction / No Flow Other _____

Please circle specific components on the diagram where issues occurred

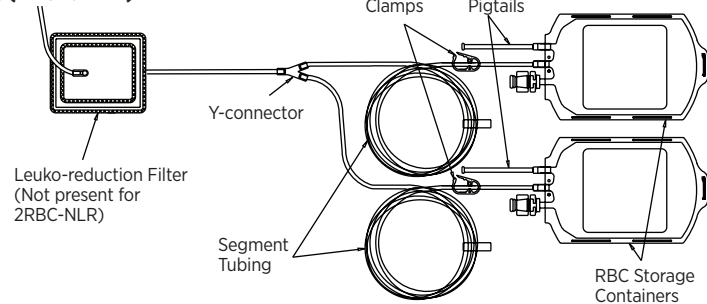


Leuko-Reduction Assembly

RBC/Plasma Kit



2RBC Kit (LR and NLR)



Additional Problem Description / Explanation

Kit Return To Fenwal

1. Check box if sample is available for evaluation.
2. Sample return box needed? Yes No Return label only
3. Do you request a letter regarding the investigation results? Yes No
4. Picture taken of defective kit? Yes No (if yes, send picture to fenwal.quality@fenwalinc.com)

Center Authorized Signature/Date: _____ Fenwal Reviewed By/Date: _____

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Please Print

Account #: _____
 Site Name: _____
 Contact Person: _____
 Operator Name: _____
 Street Address: _____
 City/State/Zip: _____
 Phone Number: _____
 E-Mail: _____
 Fax Number: _____

Notification No. (Fenwal Personnel Only)