

Whole Blood Performance Report



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

Incident Date: _____ Lot No.: _____
Product Code: _____ Filter No.: _____

When Was the Problem Detected?

☐ Before Use ☐ After Donation (at collections) ☐ Centrifugation ☐ Storage (of collected product)
☐ Donation ☐ Filtration ☐ Plasma Expression ☐ From Hospital ☐ Other (specify) _____

Problem Type (Mark all applicable) ☐ Discolored ☐ Flat ☐ Leak (solution) ☐ Mis-assembled ☐ Pre-activated Cannula
☐ Broken ☐ Cut/Slice ☐ Hole ☐ Dull/Drag ☐ Kink ☐ Leak (blood) ☐ Excess Moisture ☐ Blocked/Restricted
☐ Missing ☐ Difficult to Break ☐ Illegible ☐ Bent ☐ Separated ☐ Particulate Matter ☐ Other (specify) _____

Please answer the following questions:

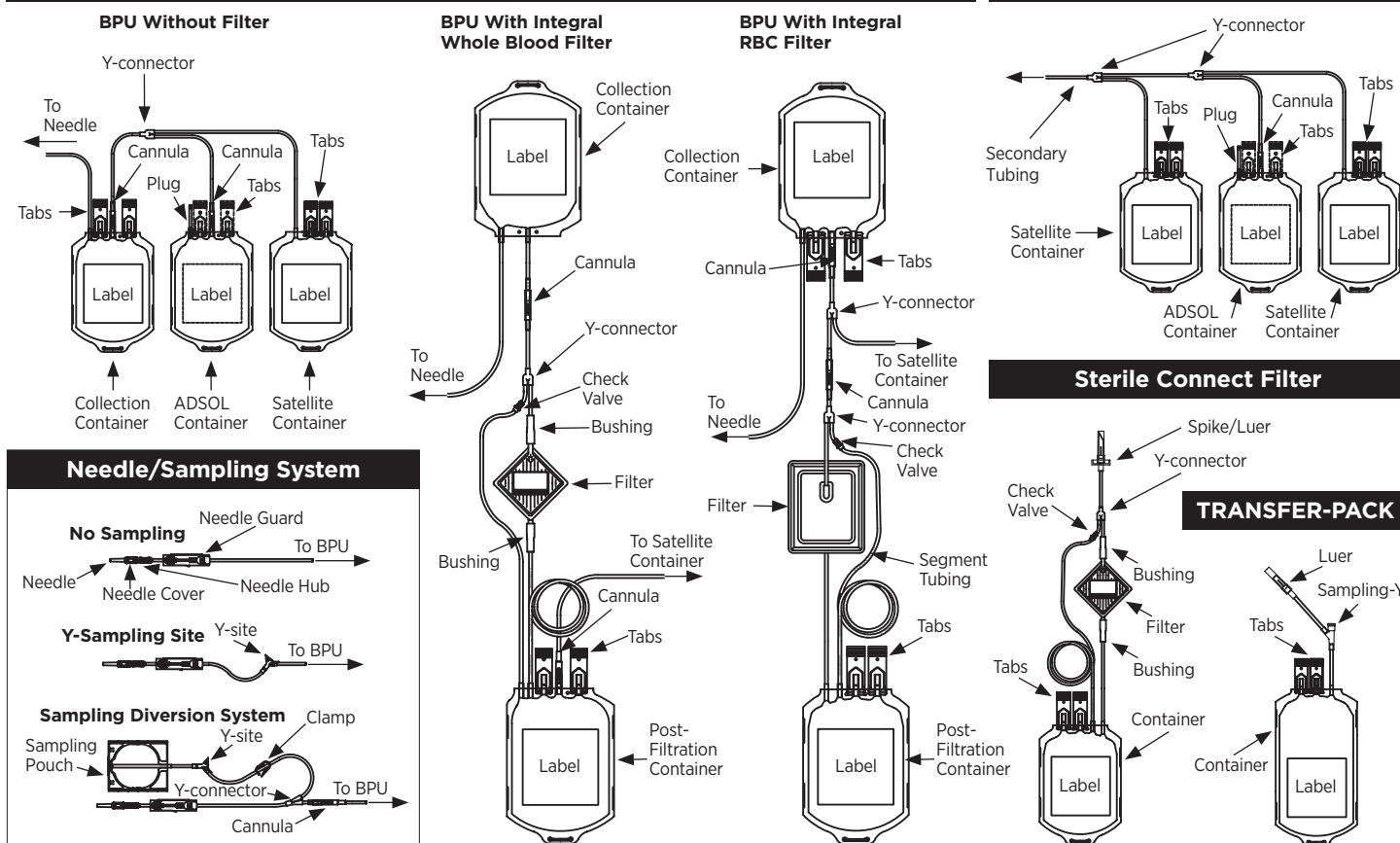
1. Was there any adverse event or injury? Yes ☐ No ☐
 2. Was the procedure successfully completed? Yes ☐ No ☐ N/A ☐
 3. If no, was the procedure stopped due to a soft goods incident? Yes ☐ No ☐ N/A ☐
 4. Was product lost? Yes ☐ No ☐ N/A ☐
- Check box if you do **NOT** wish to receive response letters. ☐

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

Please circle specific components on the diagram where incident occurred

BPU Configurations

Satellite/Secondary Containers



Additional Problem Description / Explanation

Kit Return To Fresenius Kabi

1. Sample available for evaluation? Yes ☐ No ☐
 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.