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:				
Product Code:	Filter No.:			
When Was the Problem Detect	ed?			
	,	☐ Centrifugation	☐ Storage (of colle	ected product)
☐ Donation ☐ Filtration	☐ Plasma Expression	☐ From Hospital	☐ Other (specify)_	
Problem Type (Mark all applicable	e) 🗆 Discolored 🗆 Flat	☐ Leak (solution)	☐ Mis-assembled	☐ Pre-activated Cannula
☐ Broken ☐ Cut/Slice ☐ Hole	e □ Dull/Drag □ Kink	☐ Leak (blood)	☐ Excess Moisture	□ Blocked/Restricted
☐ Missing ☐ Difficult to Break	□ Illegible □ Bent	☐ Separated	☐ Particulate Matter	☐ Other (specify)
Please answer the following qual. Was there any adverse event 2. Was the procedure successfu 3. If no, was the procedure stop 4. Was product lost? Yes ☐ No Check box if you do NOT wish to	or injury? Yes □ No □ Illy completed? Yes □ N ped due to a soft goods □ N/A □	incident? Yes □ N	lo □ N/A □ ress for letter recipien	t (if applicable)
Please circle specific compone	nts on the diagram who		<u>.</u>	с (п аррисаето)
Please circle specific compone	BPU Configurations	re incident occurre		te/Secondary Containers
				te/ Secondary Containers
BPU Without Filter	BPU With Integral Whole Blood Filter	BPU With In RBC Filter	tegral	Y-connector
Y-connector			←	Take
To Needle Cannula Cannula Tabs Tabs Plug Tabs Collection ADSOL Satellite Container Container Needle/Sampling System Needle Guard To BPU Needle Cover Needle Hub Y-Sampling Site Y-site To BPU Sampling Diversion System Clamp Y-site To BPU	Bushing	Cannula Labe Cannula ector To Needle Post- Filtration	Tubing Satellite — Container Y-connector To Satellite	Tabs Plug Cannula Tabs Tabs Plug Can
Additional Problem Description	n / Explanation			
Kit Return To Fresenius Kabi	,		ustomer Information	(nlease print)
Sample available for evaluation? Yes □ No □			Customer Information (please print) The following information is required to receive a credit	
2. Sample return box needed? Yes ☐ No ☐ Return label only ☐			Facility Name:	
3. Picture available for evaluation? Yes □ No □			Contact Person:	
Please e-mail a clear picture along with this report to			Account Number (if known):	
mdpmqa.usa@fresenius-kabi.com			Operator Name:	
Center Authorized Signature/Date:				
Janes / Landing of Janes of Ja				
			none Number:	
Fax this report to 1-888-858-2983 or	E-mail to manmas usselfes	0	ontact Person's E-mail:	
rax tilis report to 1-000-030-2903 Of	L-man to mubinda.usa@ffes	ocilino-vaniralii		

and include a copy of this form when returning a kit.