Whole Blood Performance Report



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

Additional Problem Description / Explanation Kit Return To Fresenius Kabi 1. Sample available for evaluation? Yes No Return label only Return label only Facility Name: Post-Filtration Post-Filtration Post-Filtration Container Facility Name: Facility Name:		reaction or injury								
When Was the Problem Detected? Denation After Donation (of collections)						OI No. (if applicable):				
Before Use After Donation (at collections) Centrifugation Storage (of collected product)										
Denation Filtration Plasma Excression From Hospital Other (specify)										
Problem Type (Mark all applicable) Discolored Flat Leak (solution) Mis-assembled Pre-activated Cammula Brocked (Restricted Blocked (Restrict					_			ectea proat	uct)	
Broken Out/Site Hole Duil/Orag Kink Leak (blood) Excess Molsture Blocked/Restricted Blocked/Restricted Particulate Matter Other (specify) Please answer the following questions: 1. Was there any adverse event or injury? Yes No N/A 3. If no, was the procedure successfully completed? Yes No MA 3. If no, was the procedure stooped due to a soft goods incident? Yes No N/A Check box if you do NOT wish to receive response letters. BPU Configurations BPU Without Filter BPU With integral RBC Filter Needle Cannula Garnula Total Container Needle Cannula Garnula Total Container Needle Sampling System Needle Container Container Needle Sampling System Needle Container Container Needle Sampling Diversion System Needle Sampling Site Yell's Spikkolury Spi			· · · · · · · · · · · · · · · · · · ·		<u> </u>					
Masing Officult to Break Dilegible 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 tost? Yes No N/A 5. Check box if you do NOT wish to receive response letters 6. E-mail address for letter recipient (if applicable) Please circle specific components on the diagram where incident occurred BPU Without Filter BPU With Integral Whole Blood Filter Wheeling Container Container Container Needle Connual Community Needle Container Needle Container No Sampling System No Sampling Site Yesle To BPU Sampling Diversion System Clamp Sampling Diversion System			_							
1. Was there any adverse event or injury? Yes □ No □ N/A □ 3. If no, was the procedure successfully completed? Yes □ No □ N/A □ 5. If no, was the procedure stopped due to a soft goods incident? Yes □ No □ N/A □ 5. The consector stopped due to a soft goods incident? Yes □ No □ N/A □ 5. The consector stopped due to a soft goods incident? Yes □ No □ N/A □ 6. The consector stopped due to a soft goods incident? Yes □ No □ N/A □ 7. The consector stopped due to a soft goods incident? Yes □ No □ N/A □ 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. Sampling System 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. Sampling System 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. Sampling System 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. Sampling System 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. Sampling System 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. Sampling System 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. Sampling System 7. The consector stopped due to a soft good sincident? Yes □ No □ N/A □ 7. Sampling System 7. Sampling Sys				Bent ⊔ S	eparated	⊔ Part	iculate Matter	□ Other (s	specify)	
BPU Without Filter BPU With label Blood Filter Whole Blood Filter Whole Blood Filter Whole Blood Filter Container Container Container Needle / Sampling System Needle	 Was there ar Was the product If no, was the Was product 	ny adverse event o cedure successfully e procedure stoppe t lost? Yes \(\) No \(\)	r injury? Yes 🗆 No v completed? Yes ed due to a soft go] N/A 🗆	□ No □ ods inci	dent? Yes □			t (if applica	hla)	
BPU With Integral Plug Tabs BPU With Integral Whole Blood Filter Tabs Satellite Secondary Container To BPU Tabs Plug Tabs Satellite Label Container To BPU Tabs Satellite Container Tabs Satellite Secondary Container To BPU Tabs Satellite Secondary Container Tabs Tabs Satellite Secondary Container Tabs Tabs Satellite Secondary Container Tabs Tabs Satellite Container Tabs Satellite Con	Diagra simple or						letter recipieri	т (п аррпса	DIE)	
BPU With untegral Whole Blood Filter Container Container Tabs Plug Tabs Plug Tabs Plug Tabs Satellite Label	Please circle s				iciaent occu	rrea	Catallit	to /Cocondo	w. Cantainava	
Whole Blood Filter RBC Filter To BPU Tabs Plug Tabs Plug Tabs Plug Tabs Container Container Container Container Container Container Container Needle Courr Needle Sampling System No Sampling Needle Gourr Needle Courr To BPU Transfer-Pack							Satelli	te/Seconda	ry Containers	
Needle Container Needle/Sampling System No Sampling Steel Clamp Needle/Sampling System Clamp Sampling Diversion System Clamp Sampling Container Container Container Container Container Container Container Tabs Container Container Container Container Container Container Tabs Sterile Connector Container Container Segment Tubing Bushing Container Container Container Container Tabs Customer Information (please print) The following information is required to receive a credit Facility Name: 2. Sample return box needed? Yes No Return label only Splease e-mail a clear picture along with this report to mpmqa.usa@fresenius-kabl.com Center Authorized Signature/Date: Center Authorized Signature/Date: Container Tabs Sterile Connector Container Container Sterile Container Tabs Sterile Connector Container Container Container Tabs Container Tabs Container Tabs Customer Information (please print) The following information is required to receive a credit Facility Name: Contact Person: Account Number (if known): Operator Name: Contact Person: Contact Person: Account Number (if known): Operator Name: Container Tabs Conta	BPU Wit	hout Filter						Y	-connector	
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Kit Return To Fresenius Kabi 1. Sample available for evaluation? Yes No The following information (please print) 2. Sample return box needed? Yes No Return label only Facility Name: Contact Person: Account Number (if known): Operator Name: Street Address: City/State/Zip: Phone Number: Phone	Tabs Plug Tabs Collection Collection Container Needle/S No Samplin Needle Collection Container Sampling Diver Sampling	ADSOL Satellite Container ADSOL Container Sampling System Needle Guard To BPU Needle Hub Site Y-site To BPU To BPU	To Needle Bushing Label	Container Container Container Container Container Container To Sate Container Cannula Cannula Post Filter	Cannula To Needle Filter etion	Y-connular	Container Illite Inector Illite Inector Inector Illite Inector Inecto	ADSOL Contain Spike Y-connect Filter Bushing Container Container	Label Label Label Label Satellite Container ect Filter e/Luer ctor RANSFER-PACK Luer Sampling-Y Tabs	
1. Sample available for evaluation? Yes \(\) No \(\) Return label only \(\) 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: 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: \(\)	Additional Pro	blem Description	/ Explanation							
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Please e-mail a clear picture along with this report to mdpmqa.usa@fresenius-kabi.com Center Authorized Signature/Date: City/State/Zip: Phone Number:	·			ırn label	,					
mdpmqa.usa@fresenius-kabi.com Operator Name: Center Authorized Signature/Date: Street Address: City/State/Zip: Phone Number:	3. Picture available for evaluation? Yes □ No □					Contact Person:				
Center Authorized Signature/Date: Street Address: City/State/Zip: Phone Number:						<u> </u>				
City/State/Zip:Phone Number:			COITI		I					
Phone Number:	Center Authoriz	zed Signature/Date:								
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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.