PLASMACELL-C Product Performance Report



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

		st-Harket duality Assurance at 1-000-333-0323.
Incident Date: Instrume		Software Version: UDI No.:
Batch Tag Info Time: : Batch	ch Tag No : Video	o let No:
	.:	
When Was the Problem Detected?		
	sefore Use □ Set-Un □ Inst	all Check □ Solution Prime □ Blood Prime
		on (specify cycle) After Collection Freezing
Problem Type (Mark all applicable) □ Ala		
	· · · · · · · · · · · · · · · · · · ·	Detached/Separated
•		tect Missing (not in box) Other (Specify Below)
		tect I'llssifig (not in box) Other (specify below)
Please answer the following questions: 1. Was there any adverse event or injury		
 Was there any daverse event of injury Was the procedure successfully comp 		
3. If no, was the procedure stopped due		5 □ No □ N/A □
4. Was product lost? Yes □ No □ N/A □		,
Check box if you do NOT wish to receive		
	E-mail	address for letter recipient (if applicable)
Please circle specific components on t	he diagram where incident o	occurred
Solutions		ASMACELL-C Separation Disposable Set
	er Holder AC Spike Cap	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Top Seal Hange (Hole/	(Cli+)	
Side Seal Label	AC Spike ————————————————————————————————————	V5
Label	P2 Transducer Protect	Saline Clamp Soporation Daviso
		Blood Line Sebaration Device
Bott Bott	P1 Transducer Protectom Seal	ctor P2 Line Concentrated
Injection Site Clos	sure Site	Cell Line
Plasma TRANSFER-PACK	P1 Line —	Cell Pump of Part Inco.
	a Tubing AC Stop	Reinfusion Filter Reservoir
Ton So		AC Pumb 4 Plasma Line
Luer Connector	AC Stop	Blood Clamp
Luer Cap		Hb Detector Reinfusion Line
Hanger Holes Label		Blood Pump Y3 Reinfusion Clamp
Side Seal —	Blood Line	Air Detector Plasma Clamp
Botto	om Seal	
Plasma Pooling Bottle	Batch	Tag Luer Connector
		Luer Connector Cap
Port Connector Cap Vent T		AC Line Donor Line
		Y1 — Donor Short Line
Cap Door	r Hinge Male I	Luer Cap —————Luer Connector, Male
Can Door Snaps	ving	Andrews de Navelle
Bottle Body Air Vent (Filte	ir)	Apheresis Needle le Cover Wing MasterGuard Needle Luer
Bottom Seal	Needi	le Cover Wing MasterGuard Needle Luer
Interlink Y		
Luer Cap	Needl	le Needle Tubing Luér Cap
Additional Problem Description / Expla	nation	
Kit Return To Fresenius Kabi		Customor Information (planes print)
Sample available for evaluation? Yes □ No □		Customer Information (please print) The following information is required to receive a credit
Sample available for evaluation? Yes □ No □ Sample return box needed? Yes □ No □ Return label only □		Facility Name:
Sample return box needed? Yes □ No □ Return label only □ Security □ Return label only □		Contact Person:
Please e-mail a clear picture along with this report		Account Number (if known):
to mdpmqa.usa@fresenius-kabi.com		Operator Name:
Center Authorized Signature/Date:		Street Address:
		City/State/Zip:
		Phone Number:
Fax this report to 1-888-858-2983 or E-mail to n	ndnmga usa@fresenius-kahi com	Contact Person's E-mail:

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