PLASMACELL-C Product Performance Report



Important: If reaction or injury has occurred call Fresenius	Kabi Post-Market Quality Assurance at 1-800-933-6925.
Incident Date: Instrument S/N.:	Software Version:
Product Code: Lot No.:	UDI No.:
Batch Tag Info Time: : : Batch Tag No.: : :	Video Jet No.:
	lume of Plasma Collected:mL
When Was the Problem Detected?	
\square Incoming Inspection \square Kitting \square Before Use \square Set-Up	
\Box Collection (specify cycle) \Box During Venipuncture \Box	Reinfusion (specify cycle) $__$ \Box After Collection \Box Freezing
Problem Type (<i>Mark all applicable</i>) ☐ Alarm/Alert/Help Code_	
☐ Kinked ☐ Blood/Plasma Leak ☐ Low/No Plasma Flow	
	\square HB Detect \square Missing (not in box) \square Other (Specify Below)
Please answer the following questions:	
1. Was there any adverse event or injury? Yes \(\text{No} \)	/A 🗆
2. Was the procedure successfully completed? Yes \square No \square N, 3. If no, was the procedure stopped due to a soft goods incident.	
4. Was product lost? Yes \square No \square N/A \square	ACITY TO SERVE STORY A SERVE S
Check box if you do NOT wish to receive response letters. \square	
	E-mail address for letter recipient (if applicable)
Please circle specific components on the diagram where in	
Solutions	PLASMACELL-C Separation Disposable Set
Top Seal Hanger Holder AC Spike C	
(Hole/Slit) AC Spike -	
Side Seal AC Line	Saline Clamp Y5
P2 Tran	sducer Protector Blood Line Separation Device
P1 Tran	sducer Protector P2 Line
Injection Site Bottom Seal	Concentrated
P1 Line	
Plasma TRANSFER-PACK	Reinfusion Filter
Interlink Y Plasma Tubing AC Sto	AC Pump N4 Plasma Line
Luer Connector AC Sto	
Luer Cap	Hb Detector Reinfusion Line
Hanger Holes	Blood Pump Y3 Reinfusion Clamp
Side Seal	ine Air Detector Plasma Clamp
Bottom Seal	
Plasma Pooling Bottle	Batch Tag
	Luer Connector Cap
Port Connector Cap Vent Tubing	AC Line Donor Line
Plasma Tubing Connector Port	Y1———— Donor Short Line
Connector Port Cap Door Hinge	Male Luer Cap — Luer Connector, Male
Cap Door Snaps Vent Line Tubing	Apheresis Needle
Body Air Vent (Filter)	Needle Cover Wing MasterGuard Needle Luer
Plasma Tubling Bottom Seal	
Luer Connector	Needle Needle Tubing Luer Cap
Luer Cap	record rubing Eder edp
Additional Problem Description / Explanation	
Kit Return To Fresenius Kabi	Customer Information (please print)
1. Sample available for evaluation? Yes \square No \square	The following information is required to receive a credit
2. Sample return box needed? Yes \square No \square Return label of	·
3. Picture available for evaluation? Yes \square No \square	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 F-mail to mdpmga_usa@fresenius-	kabi.com Contact Person's E-mail:

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