## **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.: Vid	
Donor Bleed No.: Volume of F	Plasma Collected:mL
When Was the Problem Detected?	
☐ Before Use ☐ Set-Up ☐ Install Check ☐ Solution Prime ☐ B	Blood Prime 🔲 Collection (specify cycle)
☐ During Venipuncture ☐ Reinfusion (specify cycle) ☐ A	After Collection
Problem Type (Mark all applicable) ☐ Alarm/Alert/Help Code	
☐ Kinked ☐ Blood/Plasma Leak ☐ Low/No Plasma Flow ☐ Cut/Sliv	
☐ Dented ☐ Installation Check ☐ Solution Leak ☐ HB Det	
Please answer the following questions:	
Was there any adverse event or injury? Yes □ No □	
2. Was the procedure successfully completed? Yes \( \Bar{\text{NO}} \text	
3. If no, was the procedure stopped due to a soft goods incident? Yes	Π Νο Π Ν/Α Π
4. Was product lost? Yes \( \text{No} \( \text{No} \) \( \text{N/A} \) \( \text{D} \)	
Check box if you do <b>NOT</b> wish to receive response letters.	
	address for letter recipient (if applicable)
Please circle specific components on the diagram where incident occ	
	ASMACELL-C Separation Disposable Set
Top Seal Hanger Holder See Saline, AC As:	sembly and Filter Device Short Line
(Hole/Slit)	Saline Line Y5
Label AC Line———	Saline Clamp
Membrane P2 Transducer Prot	ector Blood Line Separation Device
P1 Transducer Prote	ector P2 Line
Injection Site Bottom Seal	Concentrated
Blue Tip/Closure P1 Line —	Vent Filter
Saline, AC Assembly and Filter	Reinfusion Filter
Pillow AC Stop	AC Pump Reservoir
Saline Spike	Plasma Line
AC Stop—	Blood Clamp  Hb Detector
Saline Cap Breakaway Cannula Y6	Reinfusion Line
AC Spike Blood Line	Blood Pump Y3 Reinfusion Clamp
BIOOD LINE	Air Detector Plasma Clamp
AC Cap AC Filter	V2
Plasma Bags	See Plasma Bags
Hanger Holes Y7 Y8	AC Line Donor Line
Protector Clamp Clamp	Y1 — Donor Short Line
Top Seal	Clamp Clamp
Top Seal Protector	Y Connector
Side Seal → Label Label	Luer Connector Top Sample Seal Barrel
	Side Seal Pottom Soal
□ Label □ Label □ Label □ Label □ □ Lab	Needle
	Needle Luer
Bottom Seal Needle	Cover Tube Needle Tubing
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 only $\square$	Facility Name:
3. Picture available for evaluation? Yes $\square$ No $\square$	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:	Street Address:
, , , , , , , , , , , , , , , , , , ,	City/State/Zip:
	Phone Number:
Fax this report to 1-888-858-2983 or E-mail to mdpmqa.usa@fresenius-kabi.com	Contact Person's E-mail:

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