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 lag Info Time:: Batch lag No.:	Video Jet No.:
Donor Bleed No.:	mL
When Was the Problem Detected?	Duine Duine Collection (and offered)
	Prime Blood Prime Collection (specify cycle)
☐ During Venipuncture ☐ Reinfusion (specify cycle)_	
	Code Detached/Separated Noise Hole low Cut/Slice Red Plasma (Visual) Illegible Label
	□ HB Detect □ Missing (not in box) □ Other (Specify Below)
Please answer the following questions:	LITTO Detect LITHSSHIP (Not IIT box) LI Other (specify Below,
1. Was there any adverse event or injury? Yes ☐ No ☐	
2. Was the procedure successfully completed? Yes ☐ N	No 🗆 N/A 🗆
3. If no, was the procedure stopped due to a soft goods	incident? Yes 🗆 No 🗆 N/A 🗆
4. Was product lost? Yes ☐ No ☐ N/A ☐	
Check box if you do NOT wish to receive response lette	rs. LI
Blacca sivele considir community on the discussor who	
Please circle specific components on the diagram who AC Solution or 0.9% Sodium Chloride Solution	PLASMACELL-C Separation Disposable Set
	See Saline, AC Assembly and Filter Device Short Line
(Hole/Slit)	Saline Line /
Side Seal Label	AC Line Saline Clamp
Membrane	P2 Transducer Protector Blood Line Separation Device
	P1 Transducer Protector
Injection Site ————————————————————————————————————	Concentrated
Blue Tip/Closure	P1 Line Vent Filter
Saline, AC Assembly and Filter Pillow Clamp	AC Stop Reinfusion Filter
Saline Spike	AC Pumb
	AC Stop Blood Clamp
Saline Cap Breakaway Cannula Y6	Hb Detector Reinfusion Line
AC Spike \	Blood Line Reinfusion Clamp
	Air Detector
AC Cap	Y2 -
AC Filter	See Plasma Bags
Plasma Bags Hanger Holes Y7 Y8	AC Line Donor Line
Twist-Off Protector	Y1 — Donor Short Line
Top Seal	Clamp
Top Seal Top	YO Y Connector
Side Seal → Label Label	Luer Connector Top Sample Seal Barrel
Label Label Label - Side Seal	Needle Cover Plug Wing Needle Side Seal Bottom Seal
	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 ☐ No ☐	The following information is required to receive a credit
2. Sample return box needed? Yes \(\text{No} \) Return I	label only Facility Name: Contact Person:
 Picture available for evaluation? Yes ☐ No ☐ Please e-mail a clear picture along with this report t 	
mdpmqa.usa@fresenius-kabi.com	Operator Name:
Center Authorized Signature/Date:	Street Address:
ocitics Authorized Signature/ Pate.	City/State/Zip:
	Phone Number:
Fay this report to 1 000 050 2007 or F mail to make many use of re-	Contact Person's E-mail

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.