Aurora Xi 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:	IDI No:
Ratch Tag Time:	· Line No.:	UDI No.:Separator No.:
Donor Bleed No:	Volu	me of Plasma Collected:mL
	Detected?	
•	o □ Install Check □ Solut	
	☐ Reinfusion (specify cyc	
☐ Kinked ☐ Blood/Pla	sma Leak 🗆 Low/No Plasm	Help Code □ Detached/Separated □ Noise □ Hole a Flow □ Cut/Slice □ Red Plasma (Visual) □ Illegible Label
☐ Dented ☐ Installation	Check ☐ Solution Leak	☐ HB Detect ☐ Missing (not in box) ☐ Other (specify Belo
2. Was the procedure st3. If no, was the procedu4. Was product lost? Yes	e event or injury? Yes \(\) No [uccessfully completed? Yes re stopped due to a soft go	□ No □ N/A □ ods incident? Yes □ No □ N/A □
Planca circle specific co	mponents on the diagram	
_		
	Container	Plasmacell Xi Disposable Set
Top Seal Side Seal	Hanger Holder (Hole/Slit) Side Seal	Saline Line Separator
Injection Site —	Bottom Seal Closure Site	Blood Line P1 Line Tubing Keepers (purple)
Plasma Trans	fer Pack Unit	P2 Line Reservoir Vent Saline Spike/Luer
Interlink Y	Plasma Tubing	Saline Cap Reservoir
Luer Cap Hanger Holes Side Seal	Top Seal Label Bottom Seal	Tubing Keepers (inside reservoir Filter (inside reservoir) Reinfusion Line Y3 Connector Plasma Line AC Line
Plasma Pod	oling Bottle	Tubing Keeper Plasma Line Luer (gray)
	Сар	Luer Connector Cap
Port Connector Plasma Tubing Connector Port	Vent Tubing Connector Port Cap Door Hinge Cap Door	AC Spike/Luer AC Cap Y1 Connector Donor Line Donor Short Line Luer Connector, Male
Cap Door Snaps	Vent Line Tubing	Ambayasia Nasalla
Plasma Tubing Boi	dy Air Vent (Filter)	Apheresis Needle
Flasifia Tubility	Bottom Seal	Needle Cover Wing MasterGuard Needle Luer
Luer Conn	Interlink Y sector	
8		Needle Tubing Luer Cap
Additional Problem Des	cription / 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 credi
•	eeded? Yes □ No □ Retu	rn label only Facility Name:
· ·	evaluation? Yes □ No □	Contact Person:
	picture along with this repor	rt to Account Number (if known):
mdpmqa.usa@fresen	ius-kabi.com	Operator Name:
Center Authorized Signat	ure/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.