## **Platelet Collection**



## **AMICUS Separator Kit 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.:							
Product Code:	Lot No.:		PAS: N	lo □ Yes □ (Lot No.:	) W	/B Processed:	mL
When Was the Prol	olem Detected?						
☐ Set Up	☐ Collection	☐ Plasma Tran	nsfer				
☐ Prime%	☐ Reinfusion	☐ After Proce	dure/QC				
Problem Type (Mar	k all applicable)	☐ Cut/Slice	□ Kink	☐ Particulate Matter		☐ Restriction/N	o Flow
☐ Alarms (Specify)			□ Leak	☐ Platelet Aggregation	n (After 24 Hrs.)	□ Separated	
☐ Blood Leak	☐ Cracked	☐ Excess Air	☐ Missing	☐ RBC Contamination		□ Other (Specify B	elow)
Please answer the 1	ollowing questi	ons:					
1. Was there any ad	verse event or i	njury? Yes□ N	10 D				
2. Was the procedu	re successfully c	ompleted? Yes	No 🗆 1	N/A □			
3. If no, was the pro	cedure stopped	due to a soft g	oods incide	ent? Yes□ No□ N/A□			
4. Was product lost	? Yes □ No □	N/A 🗆					
Check box if you do	<b>NOT</b> wish to re	ceive response	letters. □				
				E-mail address for let	ter recipient (if	applicable)	
Please circle specif	ic components	on the diagran	n where inc	ident occurred			
	PAS Line ———— (PAS Kits Only)		Platel				
Platelet Additive			Stora Conta				
Solution		Platelet Storage	Platelet Storage				- <del></del>
		Container	Container			Double Needle Configur	ration
Anti-microbial Filter (FC Only)		Clamp					
Red Spike (FC Only)	<b>→</b> ************************************	PC	Clamp		Y-Connector Cann	ula L	Tab
		Sample Pack Y5	<b>7</b> → PC S	Sample Pack		\	4
ACD Acb		Pack Y5				Safety L	$\neg$
	Clamp	Drip A	nti-microbial Filter	Tray		(closed pos	
RBC Bag (SN Only)		Drip ************************************		Right Cassette	Advanced Kit: In	tegrated Platelet Sampling Sy	/stem
Day Day		(if present)				I look ili acca	
	•		6	1-6. Cassette Pump Tubing		Umbilicus	
Plasma					/	Separation Chamber —	$\neg \setminus \parallel$
<b>(</b>	Plasma			Middle Cassette	Tape / Upper / Joint / T	Lower Tape Joint	
			4	) Y4			
	Waste/V	VB Bag			Bearing –	Centrifuge /	77 I
				ACD Coil Air	Trap N	leedle Wings Pack Tubing	
Clear Spike (FC Only)	Clamp		2	TI Return Coil	Roller Clamp	Collection Chamber	_/
				Y3 Y3	Yı	- Gramber	
o NACL	Anti-micr	obial Drin			6_	Needle/Fistula —	
	Filter (FC		Left	Return Inlet Coil		Centrifuge Pack —	/
Note: This Diagram is a graphic re	oresentation of an AMICUS	(it. It is not intended to ac	Casse		Sample —/ Pouch	Centilidge Fack —	_
Note: FC means "Functionally Clo		vic. it is not intended to de	caracely depict a spe	cone code.			
Additional Problem	Description / I	Explanation					

## Kit Return To Fresenius Kabi

- 1. Sample available for evaluation? Yes  $\square$  No  $\square$  Not Required  $\square$
- 2. Sample return box needed? Yes  $\square$  No  $\square$  Return label only  $\square$
- 3. Picture available for evaluation? Yes □ No □ Please e-mail a clear picture along with this report to mdpmqa.usa@fresenius-kabi.com

		gnature.	

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.

## **Customer Information (please print)**

The following information is required to receive a credit