

#4

**FDA Draft Guidance Data Collection
Donor Reaction Summary
Apheresis VS Whole Blood Donations**

	Reaction Type 1	Reaction Type 2	Reaction Type 3	Total Reactions	Total Donations	Percent of reaction by donation type
WB	4946	413	7	5366	162,214	3.3%
APH	291	9	1	301	22,713	1.3%

Reaction Type:

- 1 Mild; sweating, pallor, nausea, fainting, dizziness, lightheadedness, yawning, increased nervousness, anxiousness and or hyperventilation
- 2 Moderate; same as mild including loss of consciousness, vomiting, hypotension, tachycardia, bradycardia and or mild tetany
- 3 Severe; same as mild and moderate plus severe tetany, convulsions, severe bradycardia, loss of consciousness with no response to painful stimuli, respiratory arrest, and or cardiac arrest.

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Sacramento, CA

EMS Response Times to Locations Drawing Apheresis

Location	Time:
SMBC	2 Minutes or less
RSBC	4 Minutes or less
SNBC	4 Minutes
DVBC	5 Minutes or less
GVBC	5 Minutes or less
NSBC	5 to 7 Minutes
NVBC	4 Minutes or less

#6

BloodSource
Sacramento, CA

FDA Draft Guidance Data Collection
Frequent Plasma with Platelet Crossover
Donor Chart Review

Donor ID	Donor Count Total	YTD #of <u>Frequent Plasma</u> Procedures/ Products	YTD #of <u>Platelet Products</u> (inc. plts & adult plasma)	YTD # of Procedures/ Products	Platelet Count Average		Hematocrit Average		WBC Average		TP Average		SPE Results-date drawn
					First Three Platelet Donations	Last Three Platelet Donations	First Three Donations	Last Three Donations	First Three Platelet Donations	Last Three Platelet Donations	First Three Donations	Last Three Donations	
1054546	571	14	30	27/44	223	258	42	44	4.7	4.9	6.5	6.8	6.5-8/05
1193632	701	9	70	33/79	207	247	40	39	4.4	4.0	7.0	7.0	6.0-8/05
1195837	716	17	34	34/51	247	252	47	46	6.5	5.7	7.8	7.5	6.5-9/05
1473363	102	3	47	19/50	284	316	40	41	4.0	4.3	7.3	7.6	6.4-7/05
1034844	426	27	42	41/69	266	298	45	45	7.2	8.6	7.2	7.3	6.8-9/05
1069948	105	0	28	12/28	264	300	39	39	4.4	4.3	7.5	7.5	6.9-10/05
1115427	339	13	34	26/47	239	238	38	39	5.1	4.9	7.3	7.6	6.3-10/05
1225036	67	1	51	19/52	215	229	46	45	7.1	6.7	7.4	7.2	6.1-8/05
1442174	202	1	65	18/66	247	260	46	45	5.1	4.5	8.1	8.4	6.8-8/05
1001064	373	0	70	24/70	214	225	43	45	4.0	3.9	7.2	7.1	6.5-8/05

-----Original Message-----

From: Kimberlee Chatigny

Sent: Thursday, December 08, 2005 5:22 PM

To: Patricia Kopko, M.D.

Subject: Platelet products loss...

Hi Dr. Kopko-

The number of platelet products that will be lost because the donor is only limited to 24 platelet products per year:

Sacramento:

- 3,727 platelet products. This will affect 285 donors.

North State:

- 749 platelet products. This will affect 49 donors.

North Valley:

- 319 platelet products. This will affect 31 donors.

Total All areas:

- 4,795 platelet products. This will affect 365 donors.

Total draw = 42,059

This will affect = 11.4% of draw.

MPT guidance
#8

Trish Grace

From: Sally Morgan-Gannon
Sent: Friday, October 07, 2005 1:26 PM
To: Trish Grace
Subject: FW: Platelet loss...

Sally

Sally Morgan-Gannon, MT(ASCP)SBB
Compliance Officer
BloodSource
(916) 453-3661
sally.morgan-gannon@bloodsource.org

-----Original Message-----

From: Sallie Holliman
Sent: Friday, October 07, 2005 12:58 PM
To: Group Leaders; Mike Fuller
Subject: FW: Platelet loss...

Fyi- an estimate for the response/ comments to proposed FDA guidelines !!!!!

Thank You !

Sallie Holliman, MT(ASCP)SBB
Chief Operating Officer, BloodSource
916-453-3611 FAX 916-452-6279
sallie.holliman@bloodsource.org

-----Original Message-----

From: Kimberlee Chatigny
Sent: Friday, October 07, 2005 12:47 PM
To: Trish Grace
Cc: Sallie Holliman; Patricia Kopko, M.D.; Catherine Mazzei, M.D.; Chris Gresens, M.D.; James Wagner
Subject: Platelet loss...

If Doctors are required at all locations that draw platelets...

Our current platelet goal is 42,059.

1. Shut down North State; Davis, and Grass Valley;
2. Cut out weekend draw at Roseville, Sunrise
3. Cut out weekend draw at North Valley
4. Reduce North Valley draw by 10% to allow for Dr. Howard vacation

This makes our new platelet goal 25,263.

A 40% reduction of our platelet draw.

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BloodSource
Sacramento, CA

FDA Draft Guidance Data Collection
Triple Donor Chart Review

Donor ID	Donor Total Count	YTD #of procedures	YTD #of products	Platelet Count Average	Platelet Count Average	Hematocrit Average	Hematocrit Average	WBC Average	WBC Average	Comments
				First Three Donations	Last Three Donations	First Three Donations	Last Three Donations	First Three Donations	Last Three Donations	
1103075		14	49	456	457	45	45	6.4	6.3	2002
1103075		8	28	402	404	42	43	5.5	5.9	2003
1103075	173	14	49	380	415	44	39	5.7	5.0	2004
1381659	112	24	80	324	307	43	42	5.3	4.6	2002
1088518		10	38	442	451	40	40	6.1	6.7	2004
1088518	218	12	45	438	409	40	40	5.9	5.0	2005
1129132	221	16	52	261	323	39	44	8.8	10.2	2005
1046331		19	64	306	364	41	43	5.6	5.9	2004
1046331	495	13	43	350	384	42	41	6.1	6.0	2005
1031100		14	43	216	233	43	44	5.6	4.7	2004
1031100	342	18	50	217	261	43	41	4.4	4.5	2005
1055555		12	46	270	273	40	40	7.8	6.1	2004
1055555	142	8	26	275	270	40	42	6.0	6.5	2005
1055841	195	10	34	334	327	44	42	6.7	6.5	2005
1162552	117	10	27	222	237	42	44	6.9	6.8	2005
1074165	242	23	48	203	260	44	41	3.8	3.7	2005
1211264	167	18	31	238	281	43	43	4.0	4.6	2005