Life Source Blood Services
Glenview, Illinois

Introduction: In response to the draft guidance issued by the FDA in September 2005, titled 'Collection of Platelets by Automated methods' Life Source Blood Services conducted a study to evaluate the relationship, if any, between a donor's platelet count and the frequency of donation.

Description of the study: We looked at our entire apheresis donor population during the time frame of 10/1/2004 through 9/30/2005. In that time period, the average donation frequency was 3 donations per year. Platelet counts of a subset of Group A of 524 donors who donated 3 times /year were investigated. In addition, donor platelet counts from the most frequent donors were evaluated (Group B). We also looked at a subset of Group B donors (Group C). The population of Group C consisted of those donors with a donation frequency greater than 12 donations per year and yielding a total of 25 or more products per donor, during the time frame of the study.

Results: The mean initial donor platelet count for Group A is $257 \pm 57 \times 10^3$/ul. The mean final donor platelet count for that same group is $252 \pm 55 \times 10^3$/ul.

We then looked at our most frequent donors (Group B) during the time frame 10/1/2004 through 9/30/2005, who donated at a frequency greater than 12 times per year. In that time frame the average donation frequency of 97 donors was 15.14 donations per year. The mean initial donor platelet count for Group B is $264 \pm 51 \times 10^3$/ul and the mean final donor platelet count for that same group is $267 \pm 53 \times 10^3$/ul.

We also looked at those donations associated with a donor platelet count less than 150,000/ul. In Group A there were 11 incidents in which the donor's platelet count fell below 150,000/ul. The 11 incidents involved 10 donors with 1 donor experiencing a platelet count below the acceptable limits on 2 separate occasions. This is 1.91% of the population in Group A and .64% of the donations from the population in Group A. Of these 10 donors, 6 were males with an average age of 48, and 4 were females with an average age of 42.5.

Details of the Group A donors with a low platelet count (<150,000/uL)

A 33 year old male (Donor A1) donated 3 times during the time frame of this study producing a total of 8 products as a result of these donations, 6 of which were platelets. On his original donation 10/27/2004, his platelet count was 252, at his next donation, 4 months later on 2/26/2005, his count was 140, and at his final donation during the time frame of the study on 6/11/2005 his count was 214. A 45 year old female (Donor A2) donated 3 times and yielded 7 products as a result of these donations. Of these 7 products, 5 were platelets. Donor A2 had an initial platelet count of 124 on 3/13/2005. At her next donation 4 months later on 7/10/2005, her count was 235, and on her final donation during the time frame of

the study, on 8/14/2005, her count was 289. A 35 year old male (Donor A3) donated 3 times and yielded a total of 6 products, 3 of which were platelets. At the initial donation on 11/13/2004, Donor A3 had a count of 153. He donated again on 4/9/2005 and his count was 152. On his final donation during the time frame of the study was on 8/1/2005 and at that time his count was 142. A 40 year old female (Donor A4) donated 3 times resulting in 4 products, all of which were platelets. At the initial donation on 1/23/2005 Donor A4 had a count of 249. Four months later on 4/3/2005 her count was 235, and 2 months after that on 6/22/2005 her count was 112. A 59 year old male (Donor A5) donated 3 times yielding 5 products, 4 of which were platelets. At the initial donation on 10/30/2004 Donor A5 had a count of 195. One month later on 11/2/2004 his count was 176 and 6 months later on 5/7/2005, his count was 147. A 60 year old male (Donor A6) donated 3 times yielding 6 products, 3 of which were platelets. At the initial donation on 3/27/2005, Donor A6 had a count of 138. At his second donation two months later on 5/29/2005 his count was 164, and on 5/29/2005 his count was 150. A 56 year old male (Donor A7) donated 3 times yielding 9 products, 6 of which were platelets. At the initial donation on 10/12/2004 Donor A7 had a count of 220. Two months later he donated again on 12/14/2004 with a count of 114. On 3/7/2005, his count was 226. A 41 year old female (Donor A8) donated 3 times yielding 5 products, 3 of which were platelets. At the initial donation on 2/26/2005, Donor A8 had a count of 145. Three months later on 5/7/2005, her count was 166 and on 8/13/2005 her count was 173. A 44 year old female (Donor A9) donated 3 times yielding 6 products, 3 of which were platelets. At the initial donation on 2/15/2005, Donor A9 had a count of 187, 2 months later on 4/19/2005 her count was 101, and on her final donation during the time frame of this study on 9/26/2005 her count was 129. A 45 year old male (Donor A10) donated 3 times yielding 5 products, 4 of which were platelets. At the initial donation on 4/11/2005 Donor A10 had a count of 178, his second donation occurred on 4/25/2005 and at that time his count was 170. He donated again on 5/9/2005 with a count of 126.

Details of Group B donors with a low platelet count (<150,000/uL)

In Group B there were 2 incidents in which the donor's platelet count fell below 150,000/ul. This is 2.06% of the population in Group B and .14% of the donations of the population in Group B. Both donors were males ages 64 and 46.

The first donor in this group (Donor B1) a 64 year old male donated a total of 24 times during the time frame of this study and yielded a total of 24 products as a result of these donations. His count on his initial donation on 10/4/2004 was 177. On his 18th donation during the time frame of this study on 6/6/2005, his count was 135, and on his final donation on 9/26/2005, his count was 156. At no other time during the time frame of this study did his count fall below acceptable limits. The second donor in this group (Donor B2) is a 46 year old male who donated a total of 13 times and yielded a total of 23 products as a result of these donations. On his initial donation during the time frame of the study on 10/28/2004, his

count was 237. Eleven donations later on 6/16/2005, his count was 126. On his final donation, 3 months later on 9/22/2005, his count was 217. At no other time did this donor's count fall below acceptable limits during the time frame of the study.

Low donor count and the platelet number in the donated products

We next looked at the product yield for those donations in which the donor platelet count fell below the acceptable limits and found the yield of those products to be of satisfactory content, except in the cases for which we were unable to test due to insufficient quantity (QNS) of the unit. See Table 1 below. This leads us to conclude the donor platelet counts that fell below the acceptable limits were most likely due to erroneous testing.

Table 1

Donor	Donor Platelet Count	Platelet Product Yield
A1	140	8.1
A2	124	QNS
A3	142	3.8
A4	112	QNS
A5	147	4.7
A6	138	4.5
A7	114	8.5
A8	145	3.5
A9	101	7.8
A9	129	QNS
A10	126	7.5
B1	135	3.9
B2	126	7.7

In Group B there are a total of 2527 platelet products donated during the time frame of the study. The total number of donations within Group B is 1469.The mean number of products per donor for Group B is 26 with an average of 1.7 platelet products per donation.

We then looked at a subset of Group B (Group C). The population of Group C consists of those donors with a donation frequency greater than 12 donations per year and yielding a total of 25 or more products per donor, during the time frame of the study. The population of Group C consists of 51 donors with a mean average of 33 products per year. Group C donated 880 donations resulting in 1691 platelet products giving an average of 1.9 platelet products per donation. The mean initial donor platelet count in Group C is 286 ± 49, and the mean final donor platelet count for Group C is 285 ± 51. In Group C there are no donors that experienced a decrease in their donor platelet count below 150,000/ul.

Conclusion: In summary, this study shows that donors who donate 12-24 times per year adequately maintain their platelet levels. We believe these data support the current standard of donation frequency allowing a maximum of 24 per year.

3636 Boulevard of the Allies
Pittsburgh, PA 15213-4306
Phone: 412 -209-7300

The Institute For Transfusion Medicine

December 23, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Docket #2005D-0330 -- Draft Guidance for Industry: Collection of Platelets, Pheresis by Automated Methods

Dear Sir:

ITxM (the parent company for LifeSource Blood Services—License #1025—and Central Blood Bank—License #0234) is providing our initial analysis of our platelet pheresis data from our donor base.

Thank you for the opportunity to comment.

Sincerely,

Lorraine Tarille for

Roxanne Tata
V.P. and Chief Quality Officer

/cdr