



CANADIAN BLOOD SERVICES  
SOCIÉTÉ CANADIENNE DU SANG

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2005-12-29  
CBS Control #: CBS3762

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

Dear Colleague:

**Re: Collection of Platelets by Automated Methods**  
**Draft Guidance**

Please find enclosed Canadian Blood Services' comments on "Collection of Platelets by Automated Methods", draft guidance document.

If you require clarification or further information, please do not hesitate to contact the undersigned at 613-739-2403. **Please reference the above CBS Control number in any correspondence.**

Sincerely,

for T.W. Walker, Ph.D, P. Eng.  
Executive Director  
Regulatory Affairs & Quality Audits  
Quality Assurance & Regulatory Affairs

Encl.

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**COMMENTS FROM CANADIAN BLOOD SERVICES CONCERNING  
GUIDANCE FOR INDUSTRY AND FDA REVIEW STAFF COLLECTION OF  
PLATELETS BY AUTOMATED METHODS**

2005-12-20

COMMENT #	PAGE/SECTION	EDITORIAL OR TECHNICAL	COMMENT
1	III-A Donor Selection	Technical	<p><i>You should not collect Platelets, Pheresis from donors who have ingested drugs that adversely affect platelet function. These include, but may not be limited to:</i></p> <ul style="list-style-type: none"> <li>• Aspirin (ASA)/ASA-containing drugs – 5 days from last dose (Ref. 10)</li> <li>• Non-steroidal anti-inflammatory Drugs (NSAIDS) – 3 days from last dose (Ref. 9).</li> </ul> <p>Research indicates that ASA has a half life of 6 hrs and at a 90% elimination rate it is removed in 19.8 hrs. therefore a 5 day donor deferral is excessive and would further erode Platelet, Pheresis product availability. As well the majority of NSAIDS except Piroxicam, Naproxen and Tenoxicam has a half life and a 90% elimination rate of less than 24 hrs we feel a 3 day donor deferral is also excessive.</p>
2	III-B Donor Management	Technical	<p><i>The interval between each collection of Platelets, Pheresis should be at least two (2) days with no more than two procedures in a 7-day period.</i></p> <p>There should be an exemption to permit shorter intervals for HLA-matched donors when necessary to support patient treatment.</p>
3	III-B Donor Management	Technical	<p><i>A post-donation platelet count should be performed after each collection.</i></p> <p>Suggest adding "if the facility does not routinely perform pre-donation counts" or preferably deleting the bullet. We do not perceive any benefit to counting both before and after collection.</p>

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4	III-D Medical Coverage	Technical	<p><i>Under 21 CFR 640.22(c), the procedure for collection of Platelets, Pheresis, including the availability of medical care during the donation, must conform to the standard described in the biologics license application or supplement. We believe that a physician should be present on the premises during the collection of Platelets, Pheresis to ensure that necessary medical treatment be available to the donor in a timely fashion. We interpret "present on the premises" to include a qualified physician able to arrive at the premises within 15 minutes (Ref. 11). In case of an emergency, calling 911 may be used to obtain emergency medical care and transportation to another facility for further care, but <u>we do not believe this is a sufficient substitute for an available physician as previously described.</u></i></p> <p><i>The safer and preferred method of treatment is to rely upon <u>trained emergency</u> response personnel. The possibility of transferring a donor to a Medical facility should be instigated immediately avoiding unnecessary delays at a collection site. Physicians and nurses at Blood Collection facilities are not fully trained in emergency response situations (i.e. no crash carts on site). It should also be noted that this procedure is recognizably safe, and the frequency of reactions is lower than that for Whole Blood Donors therefore it would be extremely difficult to keep physicians and nurses adequately trained.</i></p>
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5	VI-D Product Performance Qualification		<p><i>An RBC count/hematocrit be performed on Platelets, Pheresis or concurrent Plasma (when collected) containing visibly apparent RBCs to determine total packed RBC volume. You should hold Platelets, Pheresis containing more than 2 mL of RBCs until the residual WBC count has been determined and found to be less than <math>5.0 \times 10^6</math> for platelet or plasma components labelled as leukocyte reduced;</i></p> <p><i>To detect a red cell volume of 2 mL in a 300 mL product one must be able to measure 13 <math>\mu</math>L of red cells in a 2 mL sample. We question whether it is possible to make this measurement with adequate repeatability.</i></p>
6	VII-B Donor Monitoring	Technical	<p><i>Platelet Counts:</i></p> <p><i>You should notify your Medical Director when a donor has a post collection platelet count less than 100,000/<math>\mu</math>L, and you should defer the donor until his/her platelet count has returned to at least 150,000/<math>\mu</math>L.</i></p> <p><i>Suggest adding "if the facility does not routinely perform pre-donation counts" or preferably deleting the bullet. We do not perceive any benefit to counting both before and after collection.</i></p>

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<b>RBC loss per collection</b>		
<b>Donor's Initial packed RBS loss</b>	<b>Donor's Second packed RBC loss within 8 weeks</b>	<b>Eligibility</b>
Less than 200 mL	No donation or none lost	Donor is eligible to donate within 8 weeks.
Less than 200 mL	< 100 mL (total loss is < 300 mL)	Donor is not eligible to donate for 8 weeks from 2 <sup>nd</sup> loss
More than 200 mL but less than 300 mL	NA	Donor is not eligible to donate for 8 weeks.
300 mL or more of RBCs	NA	Donor is not eligible to donate for 16 weeks.

**We question the need for a 16 week deferral if the donor's haemoglobin level is acceptable after 8 weeks.**

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