## Sarah Pluff

From:

Hospital Support <a href="mailto:spitalsupport">hospitalsupport.redcross.org</a>>

Sent:

Tuesday, November 02, 2021 12:11 PM

To:

Sarah Pluff

Subject:

Low Yield Platelets

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Low Yield Platelets

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## **American Red Cross**

Dear Transfusion Services Partner,

Providing sufficient platelets to meet patient need is an ongoing challenge. As a result, the American Red Cross has been rigorously evaluating all possibilities to safely increase the supply of platelets for transfusion. We believe a viable step towards increasing platelet supply includes distributing platelets that fall just below the standard yield. As you know, the minimum yield specification of a standard apheresis platelet has been established by the FDA as  $3.0 \times 10^{11}$  platelets. The use of this dose as the standard dose is not based on specific clinical data. Moreover, in Canada and several European countries  $2.4 \times 10^{11}$  is the minimum acceptable dose for a platelet unit.

Importantly, every month, hundreds of platelet units, although not manufactured intentionally, fall short of this usual  $3.0 \times 10^{11}$  threshold and end up with yields closer to  $2.8 - 2.9 \times 10^{11}$  platelets. Given that these platelets are within 10% of the minimum yield and supply constraints are persistent, we feel that the benefits of a marginally lower platelet dose is more important than withholding these units from distribution. The available medical evidence, including the PLADO study (1,2) supports this conclusion.

The FDA recently approved the Red Cross's low yield platelet products provided the actual platelet yield is displayed on the product label allowing the transfusing physician to determine the appropriate use of the product. Therefore, beginning in December, the Red Cross will distribute fully licensed low yield LVDS and PR platelets (LYP) containing 2.8-2.9 x 10<sup>11</sup> platelets per unit to make available more platelets to serve your patients.

LYP represent less than one percent of the total Red Cross platelet inventory, however these incremental units can help alleviate shortages when used in routine distribution. No changes are being made to our manufacturing processes, and we will continue to make every effort to avoid producing LYP. The only alteration to our operation is that we will no longer discard LYP units that are incidentally produced. <u>Instead, we will include a very small number of LYP in platelet orders moving forward.</u>

Should you have questions about LYP and their clinical application, your Red Cross Medical Director is available to meet with you. Also, for your convenience please refer to the included video presentation from Dr. Baia Lasky for more information on LYP. As mentioned, we believe that most medical evidence supports this approach. However, we understand that you may come to a different conclusion. Should your facility's protocols prohibit acceptance of LYP please contact your Red Cross Account Manager before December 1st and your preference will be noted. Otherwise, the Red Cross will occasionally use LYPs, in limited quantities, to complete your platelet order.

Please note that LYPs have unique product codes; these are listed in the table below for your use.

Platelet Type	Product Code	Description
LVDS 36 PAS Platelet	EA140V00	PltsAph ACD-A PASC<3log11 LR 36h BacT
	EA141V00	PltsAph PASC<3log11 LR 36h BacT Container 1
	EA142V00	PltsAph PASC<3log11 LR 36h BacT Container 2
	EA143V00	PltsAph PASC<3log11 LR 36h BacT Container 3
	EA156V00	PltsAph ACD-A PASC<3log11 LR 36h BacT, Irr

	EA157V00	PltsAph ACD-A PASC<3log11 LR 36h BacT, Irr, Container 1
	EA158V00	PltsAph ACD-A PASC<3log11 LR 36h BacT, Irr, Container 2
	EA159V00	PltsAph ACD-A PASC<3log11 LR 36h BacT, Irr, Container 3
PR platelet	E8344V00	Apheresis PLATELETS ACD-A>PAS-C/XX/20- 24C ResLeu:<5E6 <3E11 plts  Psoralen-treated
	E9138V00	Apheresis PLATELETS ACD-A>PAS-C/XX/20- 24C ResLeu:<5E6 1st container <3E11 plts  Psoralen- treated
	E9139V00	Apheresis PLATELETS ACD-A>PAS-C/XX/20- 24C ResLeu:<5E6 2nd container <3E11 plts  Psoralen- treated
	E9140V00	Apheresis PLATELETS ACD-A>PAS-C/XX/20- 24C ResLeu:<5E6 3rd container <3E11 plts  Psoralen- treated

I encourage you to load these codes promptly so you may begin receiving these products. Product labels can be found in the <u>HPRG</u>. Each LYP is also labeled with its actual platelet yield. Thus, you will have complete transparency into the number of LYP that you receive as well as to their yield.

Introducing LYPs into routine use is only one of several mitigations the Red Cross is pursuing to strengthen the overall platelet supply. Thank you for your continued partnership and willingness to work with us to ensure that we do everything possible to provide lifesaving blood products for the patients we serve.

Thank you,

Pampus young, M.D., Ph.D.

**Chief Medical Officer** 

## Reference:

- 1. Slichter SJ, Kaufman RM, Assmann SF, et al. Dose of prophylactic platelet transfusions and prevention of hemorrhage. New Engl J Med 2010;362:600-613.
- 2. Transfusion-related adverse events in the Platelet Dose study. Kaufman RM, Assmann SF, Triulzi DJ, Strauss RG, Ness P, Granger S, Slichter SJ. Transfusion. 2015 Jan;55(1):144-53.

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