



To: Transfusion Services Managers
From: Hospital Relations
Date: October 28, 2024
Re: Important Update “Low Yield” Pooled Platelets

Update

The International Council for Commonality in Blood Banking Automation (ICCBBA) recently notified Carter BloodCare after communicating with the Food and Drug Administration (FDA) that the attribute “<3E11 plts” does not apply to pooled platelets. This “low yield” attribute only applies to apheresis platelets in the United States that do not meet the standard dose of 3.0×10^{11} . The standard dose for apheresis platelets is calculated based on an apheresis platelet being equivalent to six individual whole blood derived platelets (per the June 2024 Circular of Information and 21 CFR 640.24(c) # units $\times 5.5 \times 10^{10}$.)

The product codes EA795 and EA796 will no longer be considered acceptable products codes beginning December 1, 2024, as these codes are being redacted.

Code	Product Description
EA795	POOLED PLATELETS CPD/XX/20-24C ResLeu:<5E6 <3E11 plts Bacterial Monitoring
EA796	POOLED PLATELETS CPD/XX/20-24C Irradiated ResLeu:<5E6 <3E11 plts Bacterial Monitoring

According to the Circular of Information:

“POOLED PLATELES LEUKOCYTES REDUCED, the number of units in the pool will be indicated on the label. To determine potency of the component, assume 5.5×10^{10} platelets per unit of Platelets Leukocytes Reduced indicated on the label and $<5 \times 10^6$ leukocytes in the pool. See the label for the approximate volume.”

Please note: the verbiage “CONTAINS <3.0E11 Platelets” will no longer appear on the face label of any pooled platelet unit, and the phrase “low yield” does not apply to any pooled platelets as dictated by the FDA. Pooled platelets that do not meet the “# units $\times 5.5 \times 10^{10}$ ” yield will not be available for transfusion. The following codes will be used for all pooled platelet products as previously provided.

- EA789 POOLED PLATELETS|CPD/XX/20-24C|ResLeu:<5E6|4 units|Bacterial monitoring
- EA790 POOLED PLATELETS|CPD/XX/20-24C|ResLeu:<5E6|5 units|Bacterial monitoring
- EA791 POOLED PLATELETS|CPD/XX/20-24C|ResLeu:<5E6|6 units|Bacterial monitoring

- EA792 POOLED PLATELETS|CPD/XX/20-24C|Irradiated|ResLeu:<5E6|4 units|Bacterial monitoring
- EA793 POOLED PLATELETS|CPD/XX/20-24C|Irradiated|ResLeu:<5E6|5 units|Bacterial monitoring
- EA794 POOLED PLATELETS|CPD/XX/20-24C|Irradiated|ResLeu:<5E6|6 units|Bacterial monitoring

The term “low yield” will continue to be applied to low yield apheresis platelet units that do not meet the minimum yield of 3.0×10^{11} as that process and distribution does not change.

Original Communication from July 2024 is Included for Reference

Background

Carter BloodCare offers whole blood derived pooled platelets as a therapeutic equivalent to apheresis platelets. Additionally, some of these products contain a platelet yield that falls below 3.0×10^{11} which is considered the standard yield for a unit of apheresis or pooled platelets. To increase the community supply and availability of platelet products, we are offering low yield pooled platelets for transfusion needs.

Client Action

Carter BloodCare should have this product available on September 10, 2024 and as manufacturing conditions allow. Please be prepared to accept low yield pooled platelets into your transfusion service.

Low Yield Pooled Platelets

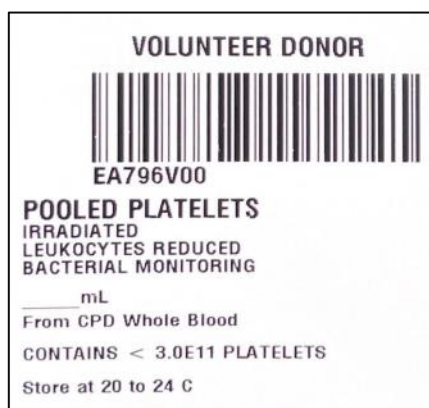
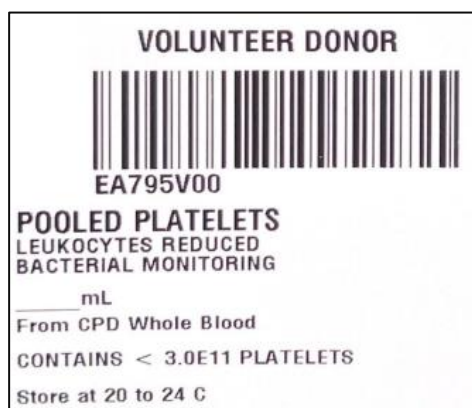
- Imugard™ platelets are a pool of whole blood-derived platelet concentrates prepared by the blood center. The pool is sampled for bacterial contamination detection by the same method used for apheresis platelets, and the pool is leukoreduced. The pooling method and storage bag allow for 7-day storage. All units in the pool will have the same ABO type. The units may have the same Rh type or may be of mixed Rh type, in which case they will be labeled as “pooled” Rh type.
- Each Low Yield Pooled Platelet will contain a yield between $2.5 - 2.9 \times 10^{11}$. The final product yield will be documented on each individual unit.
- This product is not eligible for returns. Hospital Services/Distribution will confirm acceptance with your laboratory prior to shipping out any low yield products.

- Pricing will mirror the low yield apheresis platelet products (E5075) listed on your Blood Service Fee Schedule.

ISBT Code Product Description

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Product Code Barcode Examples



Carter BloodCare’s Medical Director team is available for consultation and to address any questions your clinician team may have regarding these platelets.

Please contact hospitalrelations@carterbloodcare.org with any questions or concerns.