Apheresis Platelets - US Guidance

Use of Container Codes versus Use of Division Codes

The following information reflects ICCBBA’s current understanding for labeling Apheresis Platelets in the US. This leaflet addresses items not covered in the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128, Version 3.0.0. Users must understand the terms and definitions in the table below to understand this guidance.

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<td>Platelet Apheresis Terminology</td>
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<td>Note: The following terminology is specific to US apheresis manufacturing and may not represent use of these words in other contexts (including other ISBT 128 contexts).</td>
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<td>Reference: Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007)</td>
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General Labeling Conditions

**Single Collection:** If a collection results in only one product with a yield of $\geq 3 \times 10^{11}$, Product Description Codes without container Attributes (e.g., E3077 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6) should be used.

If the single product is divided, the products should be labeled as divided components. That is, the character in the 7th position of the Product Code must change from a 0 (zero) to an upper case ‘A’ for one product and an upper case ‘B’ for the other.

Additionally, any product that has the platelet yield of $<3.0 \times 10^{11}$ platelets is considered “low yield”. Product Description Codes for these platelets shall include the Attribute “<3E11 plts” from the ‘Dosage — Additional Information Attribute Group.’ The actual platelet count on these units shall appear on the label. Alternatively, if the product is intended for pediatric use, the Attribute “pediatric dose” shall be used. In both instances, the actual platelet count shall appear on the label.

If a division results in one product with $\geq 3 \times 10^{11}$ and one $< 3.0 \times 10^{11}$, it does not matter which product becomes A0 and which becomes B0. However, it is recommend that facilities develop a policy for which Division Code is assigned to the “standard” product and which is assigned to the low yield product, and then be consistent in following their policy.

**Example:** An apheresis platelet collection with a platelet count of $5.8 \times 10^{11}$ is divided into two products. One has a count of $3.1 \times 10^{11}$ and the other has a count of $2.7 \times 10^{11}$.

- Original Collection = E3077V00 (Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6, not divided)
- Divided product with $3.1 \times 10^{11}$ platelets = E3077VA0 (Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6, divided)
- Divided product with $2.7 \times 10^{11}$ platelets = E4643VB0 (Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|<3E11 plts, divided)
Double or Triple Apheresis Collections

As defined, multiple products from a platelet apheresis collection must each have a yield of ≥3 x 10^{11}. Each of these products with yields of ≥3 x 10^{11} shall have a Product Description Code with a container Attribute. For example:

- E3087 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container
- E3088 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container
- E3089 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container

If one of these products is subsequently divided, Division Codes (7th and 8th position of the Product Codes) shall be used. Further, if a divided product has a yield of <3 x 10^{11} a Product Description Code with the Attribute “<3E11 plts” from the ‘Dosage — Additional Information’ Attribute Group shall be used. Alternatively, if the product is intended for pediatric use, the Attribute “Pediatric dose” shall be used. In both instances the actual platelet count shall appear on the label.

For example:

- The Product Description Code for this product would be: 
  E4646 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts

  The full Product Code for this divided product would then be: E4646VA0

  OR

- The Product Description Code for this product would be: 
  E7966 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|Pediatric dose

  The full Product Code for this divided product would be: E7966VA0.

Example Scenario -

If a component with a yield of ≥3 x 10^{11} labeled with a container Attribute is further divided for pediatric use, the unit will retain the container Attribute and be assigned a Division Code. In this situation, there are two labeling options: (1) use the low volume Attribute “<3E11 plts” or (2) use the Attribute “Pediatric dose”. In both instances, the actual platelet count shall appear on the label.
Example for Option 1 – Use of <3E11 plts Attribute

- E3056 = Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container
- E4648 = Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|<3E11 plts

Example for Option 2 - Use of ‘Pediatric dose’ Attribute

- E7006 = Apheresis PLATELETS|ACD-A>PAS-C/XX/20-24C|Irradiated|ResLeu:<5E6|1st container
- E7977 = Apheresis PLATELETS|ACD-A>PAS-C/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|Pediatric dose
Exception to General Labeling Conditions

Relabeling Platelet Units after Quality Control Testing

A double or triple collection that results in more than one transfusable container believed to yield more than $3.0 \times 10^{11}$ platelets will be labeled with Product Description Codes that have container Attributes. If Quality Control is subsequently performed (near the time of outdating or distribution) and it is determined that one container has a yield of $<3.0 \times 10^{11}$ platelets, this unit shall be given a low yield Attribute, but does not need a Division Code.

Example: An apheresis platelet collection that results in three containers all believed to have yields of $\geq 3 \times 10^{11}$ is later tested for quality assurance. One unit reveals an actual yield of $2.9 \times 10^{11}$ platelets. The other two products have already been distributed. The low yield product shall be assigned a new Product Code indicating the low yield (either $<3E11$ or, if intended for pediatric use, “Pediatric dose”). In this scenario the product would retain the container Attribute even though the product does not contain a full adult dose. Since this product is low yield, the actual platelet count must appear on the label.

Original Collection

9.3 $\times 10^{11}$

E3077V00

1st Container
*Presumed Platelet Count $>3.0 \times 10^{11}$

E3087V00

2nd Container
*Presumed Platelet Count $>3.0 \times 10^{11}$

E3081V00

3rd Container
*Presumed Platelet Count $>3.0 \times 10^{11}$

E3089V00

Count Performed

3rd Container Platelet Count $<3.0 \times 10^{11}$

E4646V00

Product given a low yield attribute “$<3E11$ plts”, after QC determined the actual platelet count

Original Collection is E3077 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6
- E3087 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container
- E3081 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Plasma reduced|2nd container
- E3089 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container
- E4646 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts