

# 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.**

<b>Glossary</b>	
<b>Platelet Apheresis Terminology</b>	
<p>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).</p> <p>Reference: <i>Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007)</i></p>	
<i>Single Collection</i>	<i>A type of collection that results in one transfusable apheresis platelets component with a platelet yield of <math>\geq 3 \times 10^{11}</math> or <math>&lt; 3 \times 10^{11}</math> (low yield).</i>
<i>Double Collection</i>	<i>A type of collection that results in two equal transfusable apheresis platelets components, each with platelet yields of <math>\geq 3 \times 10^{11}</math> (1st and 2nd Containers). The two components may have either been collected during the apheresis process or produced by the post-collection separation (splitting) of the single parent container.</i>
<i>Triple Collection</i>	<i>A type of collection that results in three equal transfusable apheresis platelets components, each with platelet yields of <math>\geq 3 \times 10^{11}</math> produced by the post-collection separation (splitting) of the single parent container (1st, 2nd and 3rd Containers) .</i>
<i>Divided Component</i>	<p><i>A component that results from the separation (division) of a transfusable apheresis platelets component obtained from a single, double, or triple collection into components with lower volumes and counts. These resultant products are designated with division codes such as A0 and B0 in positions 7 of the ISBT 128 Product Code. (If a divided product is again divided, Position 8 of the ISBT 128 Product Code would be changed to the appropriate lower case letter.) Divided products may have platelet yields that are either <math>\geq 3 \times 10^{11}</math> or <math>&lt; 3 \times 10^{11}</math> (low yield).</i></p> <p>(Note: This definition applies only to divided apheresis platelets. The term “divided” may be used with other components for which this definition does not apply.)</p>

## General Labeling Conditions

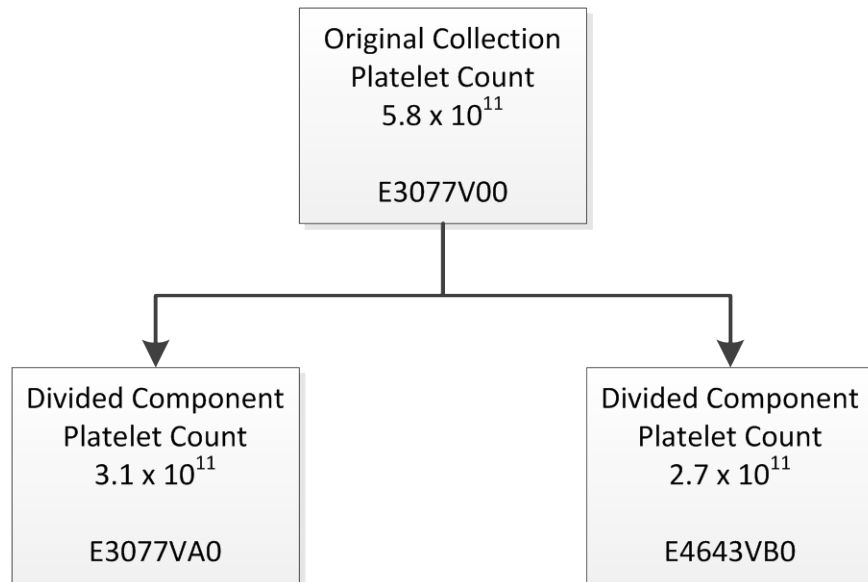
**Single Collection:** If a collection results in only one product with a yield of  $\geq 3 \times 10^{11}$ , Product Description Codes without container Attributes (e.g., E3077 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6) should be used.

If the single product is divided, the products should be labeled as divided components. That is, the character in the 7<sup>th</sup> 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 recommended 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  $\geq 3 \times 10^{11}$ . Each of these products with yields of  $\geq 3 \times 10^{11}$  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 (7<sup>th</sup> and 8<sup>th</sup> position of the Product Codes) shall be used. Further, if a divided product has a yield of  $< 3 \times 10^{11}$  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

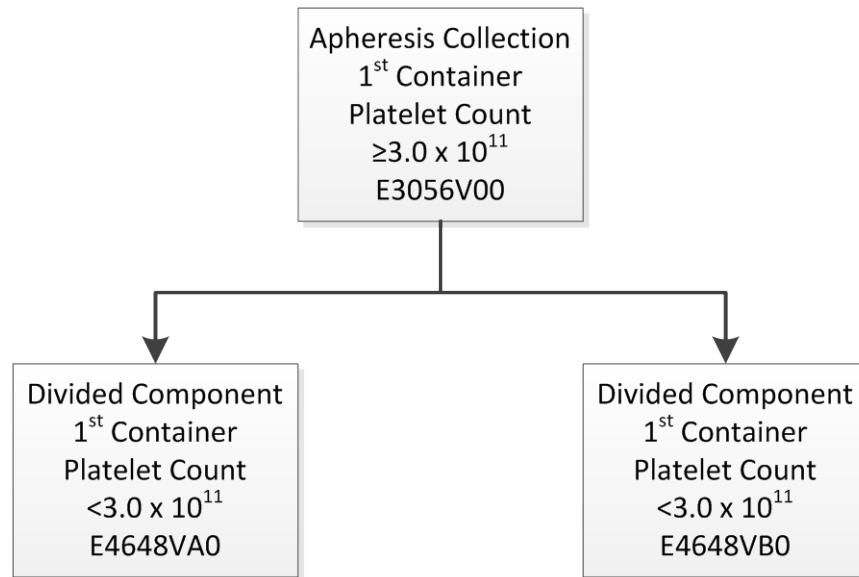
The Product Description Code for this product would be:

E7966 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|Pediatric dose

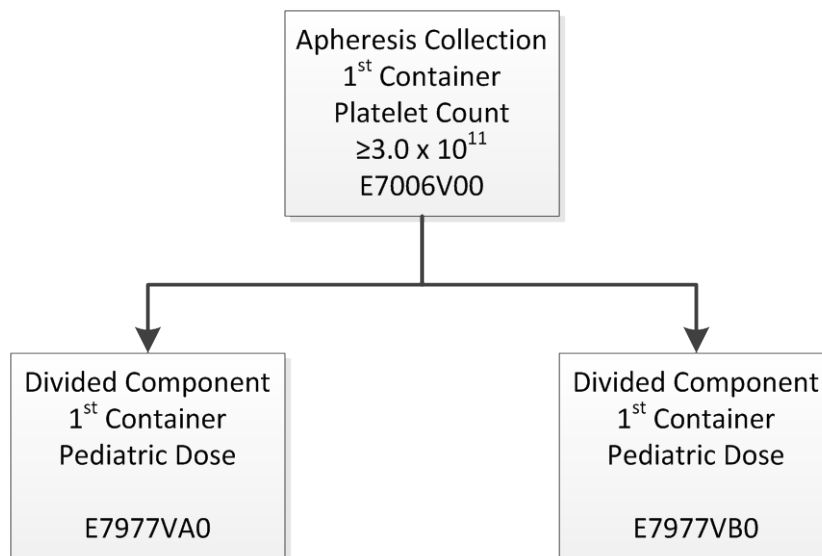
The full Product Code for this divided product would be: E7966VA0.

### Example Scenario -

If a component with a yield of  $\geq 3 \times 10^{11}$  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**

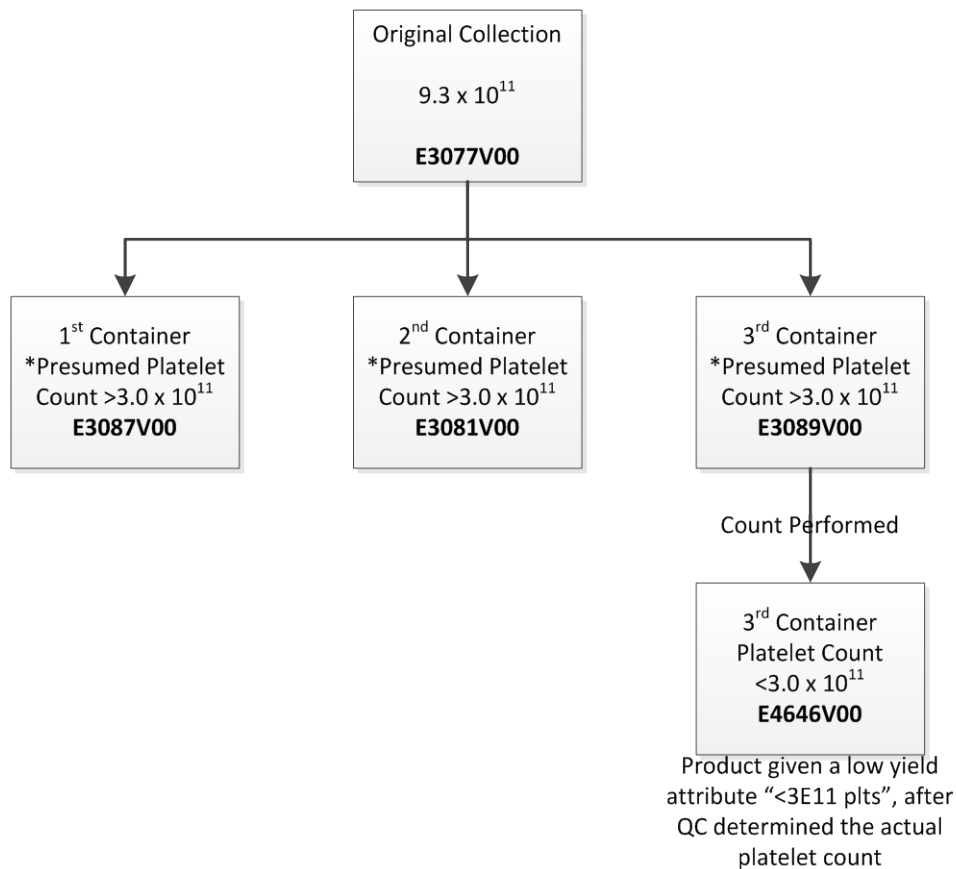
- E7006 = Apheresis PLATELETS|ACD-A>PAS-C/XX/20-24C|Irradiated|ResLeu:<5E6|1st container
- E7977 = Apheresis PLATELETS|ACD-A>PAS-C/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|Pediatric dose

## 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 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