



**To:** Transfusion Services Managers  
**From:** Hospital Relations  
**Date:** January 18, 2021  
**Re:** UPDATE: Apheresis Platelets - Large Volume Delayed Sampling (LVDS)

**Update:**

On December 17, 2020, the FDA modified the recommended date to implement the bacterial risk control strategy guidance from April 1<sup>st</sup> to October 1, 2021. Carter BloodCare intends to implement the plan below on June 22, 2021. The associated pass-through cost will also be effective on June 22, 2021.

**Overview:**

In September 2019 the FDA published the final guidance document, Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion outlining multiple options to control the risk of bacterial contamination in room temperature stored platelets intended for transfusion. Carter BloodCare plans to implement the large volume delayed sampling single-step strategy using the FDA approved, bioMerieux® BACT/ALERT system. The go-live date is tentatively scheduled for March 25, 2021.

**Impact to Clients:**

- Apheresis platelets will be labeled with a seven day expiration.
- The guidelines stipulate that we must hold these platelets for 48 hours prior to sampling and then incubate for an additional 12 hours before distribution to hospitals.
- New ISBT product codes are required and are listed below for your reference.
- A pass-through cost of \$45 will be added to the apheresis platelet fee effective April 1, 2021.
- Acrodose® platelet expiration, cost and bacterial detection strategy remains unchanged.
- Rapid bacterial testing will be discontinued following full implementation of LVDS.

**Client Action Required:**

- Build and validate 7-day apheresis platelet ISBT product codes.
- Notify administration of the fee increase.
- In cases where platelet availability is limited, we might have to import pathogen reduced platelets. There will be a \$150 pass through fee for these products.

ISBT Product Code

ISBT Code	ISBT Product Description
E5030	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5E6 Bacterial

	monitoring
E5031	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5E6 1st container Bacterial monitoring
E5032	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5E6 2nd container Bacterial monitoring
E5033	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5E6 3rd container Bacterial monitoring
E5034	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5E6 Bacterial monitoring
E5035	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5E6 1st container Bacterial monitoring
E5036	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5E6 2nd container Bacterial monitoring
E5037	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5E6 3rd container Bacterial monitoring
E5073	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5E6 <3E11 plts Bacterial monitoring
E5075	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5E6 <3E11 plts Bacterial monitoring
E5370	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5E6 1st container <3E11 plts Bacterial monitoring
E5371	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5E6 2nd container <3E11 plts Bacterial monitoring
E5372	Apheresis PLATELETS ACD-A/XX/20-24C ResLeu:<5E6 3rd container <3E11 plts Bacterial monitoring
E5532	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5E6 1st container <3E11 plts Bacterial monitoring
E5533	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5E6 2nd container <3E11 plts Bacterial monitoring
E5534	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5E6 3rd container <3E11 plts Bacterial monitoring

**Questions and Additional Information:**

Please contact [hospitalrelations@carterbloodcare.org](mailto:hospitalrelations@carterbloodcare.org) with any concerns.