



January 25, 2024

In accordance with December 2020 Guidance for Industry recommendations published by the Food and Drug Administration (FDA), "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion", LifeShare Blood Center is providing the following information:

1. To meet these requirements for platelets, LifeShare Blood Center uses chlorohexidine to prepare the phlebotomy site and diversion pouches to prevent normal skin flora from entering the final product. Additionally, one of the following strategies will be used identify or mitigate bacterial contamination in platelet products:
 - a. Single-step, large volume, delayed sampling (LVDS) for bacterial culture performed no sooner than 36 hours post collection for products with a 5-day expiration date.
 - b. Single-step, large volume, delayed sampling (LVDS) for bacterial culture performed no sooner than 48 hours post collection for products with a 7-day expiration date.
 - c. Cold storage at 1-6°C
2. Apheresis Platelet Storage.
 - a. LVDS-36. These platelets may be stored in either 100% plasma or a storage fluid containing 65% Intersol/35% Plasma in a container approved by the FDA for either 5 or 7 day storage. Storage conditions are 20-24°C with gentle agitation. Storage period is limited to 5 days post collection.
 - b. LVDS-48. These platelets are stored in 100% plasma and in a storage container approved by the FDA for storage up to 7 days. Storage conditions are 20-24°C with gentle agitation. Storage period is limited to 7 days post collection.
 - c. Cold Stored Platelets are placed at 1-6°C within 2 hours of collection and maintained at 1-6°C for up to 14 days post collection. Gentle agitation is not required for cold stored platelets.

For additional information regarding processing, storage conditions or storage periods for apheresis platelet products, please contact your local LifeShare Blood Center Hospital Services representative.

A handwritten signature in blue ink that reads "Wendell Jones".

Wendell Jones, MS, MT(ASCP)SBB, CQA(ASQ)
Executive Director, Quality and Regulatory Services

Apheresis Platelet Processing & Storage: Jan 2024