American Red Cross

The American Red Cross Approach to Platelet Safety

Implementation Plan for FDA Bacterial Control Strategies

July 15, 2020

Platelets offer essential, lifesaving treatment, but are inherently complex to supply. Growing demand coupled with a limited donor pool and short shelf life make for unique operational challenges. These challenges are further intensified by platelets' room temperature storage contributing to potential bacterial contamination. For several years, the blood industry and the Food and Drug Administration (FDA) have struggled to balance platelet safety and product availability. After several iterations, the FDA issued final Guidance for Industry on Bacterial Risk Control Strategies in September 2019 that outlines approaches blood providers and transfusion services must adopt in order to mitigate this risk.

To maximize the safety and availability of its platelet supply, the American Red Cross is transitioning to a complete pathogen reduced (PR) platelet inventory. After careful evaluation of our supply chain in conjunction with customer feedback requesting a convenient, ready-to-use platelet product, the Red Cross has determined pathogen reduction offers the most complete platelet solution for meeting the Guidance and protecting patient care.

As the largest provider of platelets in the U.S., the Red Cross has a duty to ensure continuity of supply. As such, we have developed a judicious changeover plan that will allow Red Cross to ramp to a full PR platelet supply over an extended period with minimal disruption to platelet availability. Throughout our transition, Red Cross will augment its PR inventory with a compliant platelet product bacterially tested through large volume delayed sampling (LVDS) with a five-day shelf life.

Platelet Products:

With the implementation of LVDS testing, the Red Cross will offer only pathogen reduced platelets and LVDS five-day platelets stored in PAS and plasma (temporarily) to simplify inventory management and reduce the cost and complexity associated with providing multiple products. Conventional single donor platelets (SDPs) are being modified by LVDS testing and they along with pathogen reduction are being offered in compliance with the FDA Guidance.

Hospitals must be prepared to accept any of these products or risk limited order fulfillment.

Timeline:
On February 1, 2021, the Red Cross will implement LVDS testing on all platelet products not pathogen reduced. This approach will guarantee customers a fully compliant platelet, without any required intervention by hospitals, well in advance of the FDA's March 31st deadline.

At the time of implementation, Red Cross platelet inventories will be approximately 40% pathogen reduced, 60% LVDS. We will be systematically increasing our pathogen reduced supplies over the course of the subsequent two years until we reach a 100% pathogen reduced supply in 2023. The transition timeline is purposeful in its duration to allow hospitals adequate time to prepare for these changes and to minimize any impact to supply.

Service Agreement Modifications and Fees:
LVDS testing presents additional expenses associated with the equipment, supplies and staffing required to perform both aerobic and anaerobic culturing. Lost products due to a higher rate of false positives, impacted products per donation split rates, diminished shelf life and the recruitment/collections expense to replace these lost volumes are also factored into the cost of implementing LVDS testing. Therefore, LVDS platelets will be assessed an additional $83.00 per unit fee.

This communication serves as notification, effective February 1, 2021, the Fee and Services schedule and Return, Transfer and Credit Policy in the Blood Services Agreement is modified, and your platelet fees will be increased by the following:

Fees and Services Schedule Modification

LVDS platelet fee = Contracted SDP fee +$83.00
Pathogen Reduction platelet fee = Contracted SDP fee + $150.00

Return, Transfer and Credit Policy Modification

Returns and stock rotations of PR and LVDS platelets will cease. Product stewardship necessitates that platelet inventories be managed stringently to avoid wastage.

Please retain a copy of this notification for your contract files.

Order Fulfillment:
Red Cross will be managing LVDS and PR platelet inventories collectively to maximize supply. As determined by availability, Red Cross will attempt to fill orders based on hospital requests. However, if we are unable to complete an order in full, the balance will be substituted with either PR platelets or LVDS platelets. The available substitutes will be assessed the applicable fees.

To ensure platelet orders are processed swiftly, please prepare your hospital now to receive both LVDS and PR platelets.

Immediate Actions:
Despite this change being months away, we want to provide ample time for your hospital to prepare. Over the course of the next several weeks your account manager will schedule a meeting to discuss the Red Cross's approach to platelet safety and how we can work together to prepare your hospital for these upcoming changes. During this time, we will review:

- Your hospital timeline for transition to pathogen reduced platelets
- A prepared Hospital Implementation guide for pathogen reduced platelets
- Updates required for your lab and billing systems to accept PAS, LVDS and pathogen reduced platelets

Your Red Cross Medical Director is also available to address any questions you may have regarding these product choices.

Improving platelet safety and increasing access to a consistent, readily available inventory is a chief priority for the American Red Cross, and we are confident that pathogen reduction is the optimal solution to maximize the safety and sustainability of platelets. Hospitals and blood centers gain the shared benefit of operational simplicity while advancing patient care through safer platelets.

Chris Hrouda, president, Biomedical Services at the American Red Cross