The American Red Cross Approach to Platelet Safety

Updated Implementation Plan for
FDA Bacterial Control Strategies
December 23, 2020

Earlier this year, the American Red Cross announced its approach to enhancing platelet safety and addressing the Food and Drug Administration's (FDA) Guidance on Bacterial Risk Control Strategies by providing large volume delayed sampling (LVDS) platelets beginning February 1st. In recognition of the extraordinary work effort required of hospitals to respond to the COVID-19 pandemic, the Red Cross has elected to postpone its planned start date. Considering the FDA's revised timeline for implementation, the Red Cross will begin performing LVDS 36 hours with a five-day shelf life on June 1, 2021, for any platelet not pathogen reduced (PR). We hope this extension will provide your hospital the necessary time to prepare your lab systems and staff for these important changes.

We remain steadfast in our commitment to improving the safety and availability of platelets. We will continue to employ our current methods to test non-PR treated platelets at 24 hours using both an aerobic and anaerobic bacterial culture medium followed by a 12-hour hold as recommended by the FDA until we transition to LVDS. We will also continue to expand our PR platelet supply to provide the safest products possible and to meet the rapidly growing demand. We expect our distributions to be split 50/50 between PR and LVDS at the time of implementation.

While the Red Cross has already undertaken much of the necessary work and investment to ensure compliance, we understand that the pandemic has added significant additional clinical and operational challenges and we believe that postponing our implementation is the right decision. By design, we will transition our system to LVDS 36 testing in advance of the summer holidays and the anticipated summer supply challenges to avoid any disruption to service and because patient safety is too important to delay any further.

As we draw closer to June 1st, we will provide you with more details on our implementation. Until then, we encourage you to continue to work with your IT department and your LIS vendors to ensure you can receive PR and LVDS 36

platelets when the time comes. To assist you, please access our Hospital Partner Resource Guide to obtain ISBT product codes, sample labels, and implementation materials.

The Red Cross seeks to partner with you to ensure your readiness to meet patient needs. We are working diligently through the pandemic challenges to maximize both the availability and safety of platelets. We believe the additional time will secure a seamless transition to a fully compliant, ready-to-transfuse platelet supply beginning in June. Should you have any questions or need assistance in preparing for PR and LVDS 36 platelets, please contact your Account Manager or Medical Director.

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