Bacterial Risk Control Strategies to Enhance the Safety and Availability of Platelets for Transfusion

Since March 1, 2004, the San Diego Blood Bank (SDBB) has been performing culture-based quality control bacterial detection testing using the BacT/ALERT system for all apheresis platelet collections. In 2021, SDBB implemented two different technologies in order to enhance bacterial mitigation activities; the Pathogen Reduction Technology (PRT) and the Large Volume, Delayed Sampling (LVDS) strategy. Additional methods employed to reduce bacterial contamination of apheresis platelets collected at SDBB include the use of a donor history questionnaire to prevent blood collection from donors with increased risk of infection, the performance of a donor mini-physical that includes temperature measurement of donors, preparation of phlebotomy site with anti-microbial skin solutions, and the use of a diversion pouch during collection to capture the initial flow of blood following needle insertion.

Large Volume, Delayed Sampling (LVDS) Strategy: Apheresis platelets using the LVDS strategy are sampled, at a minimum 48 hours following collection. A sample of approximately 16mL is aseptically collected from each apheresis platelet bag and is inoculated evenly into aerobic and anaerobic culture media bottles. The bottles are incubated for up to 5 days using the BacT/ALERT system. Apheresis platelet components manufactured using the LVDS strategy are acceptable for release after all infectious disease testing results have been received, the units have been sampled, the associated culture bottles have been loaded into the BacT/ALERT incubator, and a minimum incubation period of 12 hours after inoculation has been completed.

In the event that any of the inoculated culture bottle indicators are read as "positive" then all components from the “positive” collection are immediately quarantined. However, if any involved components have been distributed to hospitals, the consignees are immediately notified and an attempt to recall components is initiated. Hospital consignees should implement their own internal procedures for physician notification and recipient follow-up in the event that “positive” components have been transfused prior to the recall attempt.

All “positive” culture bottles are sent to a contracted microbiology laboratory for subculture to confirm the presence of microorganism and to identify the microorganism present. A final summary of findings is prepared and reviewed by the SDBB Chief Medical Officer. Final reports are forwarded to hospital consignees in cases where platelets have been transfused and culture results are confirmed positive for microbial growth.

Pathogen Reduction (PRT) Technology: Apheresis platelets manufactured using the PRT method are treated using the CERUS INTERCEPT Blood System to inactivate a broad spectrum of microorganisms. The process uses a chemical agent (amotosalen) that is activated by ultraviolet light to bind nucleic acids so that DNA is unable to replicate. Because of the general nature of the inactivation technology, the process is effective against many infectious agents, including viruses, bacteria, parasites, and protozoa. The extent of the inactivation, and thus the effectiveness to prevent transfusion-transmitted infections, varies among different microorganisms. The process also inactivates donor T-lymphocytes that my cause transfusion-associated graft- versus- host disease (TA-GVHD) PRT platelets may be used as an alternative to gamma irradiation for the prevention of TA-GVHD.