

BACTERIAL CONTAMINATION RISK MITIGATION STRATEGY

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To reduce the incidence of bacterial contamination of platelets and septic transfusion reactions that could result, LifeStream utilizes the following multifaceted strategy, in compliance with AABB, FDA, and College of American Pathologists (CAP) standards and references:

- We collect all apheresis platelet products using techniques designed to minimize the risk of contamination. This includes site preparation, use of sterile equipment, and diversion of the first portion of the collection.
- After a 24-hour post-collection waiting period, we culture all platelets using the FDA-approved BioMerieux BacT/ALERT 3D system.
 - We inoculate a minimum of 8 mL of product in aerobic culture medium under sterile conditions.
 - We hold culture bottles at least 0.5 days after product expiration.
- Following culture inoculation, we hold platelet products a minimum of 12 hours to minimize risk of release of a product with heavy contamination.
- Immediately upon notification of a result suggesting contamination, we initiate an investigation and take action to safeguard patients.
 - All in-house platelet and associated products are quarantined
 - If a product has been shipped, we notify the hospital promptly to quarantine and return the product.
 - If the product has been transfused, we supply an information sheet to guide conversations with clinical staff.
 - A local, CAP-accredited microbiology laboratory identifies any organisms in the culture media.
- We provide final results and interpretation to all facilities that have transfused a unit implicated as possibly contaminated.

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