

## **BACTERIAL CONTAMINATION RISK MITIGATION STRATEGY**

**Updated December 2021**

To reduce the incidence of bacterial contamination of platelets and the risk of a resultant septic transfusion reaction, LifeStream utilizes the following multifaceted strategy in compliance with AABB standards, College of American Pathologists (CAP) checklist, and FDA regulations including the *Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion—Guidance for Industry*, December 2020:

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 48-hour post-collection waiting period, we culture platelets using the FDA-cleared BioMerieux BacT/ALERT systems.

- We inoculate platelet product samples in both aerobic and anaerobic culture media under sterile conditions as stipulated by the December 2020 FDA guidance (i.e. LVDS  $\geq$ 48 hours single step strategy).
- We hold the platelet product for a minimum of 12 hours after sample inoculation before distribution as stipulated by the December 2020 FDA guidance.
- We hold culture bottles at least 0.5 days after product expiration.

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 and recalled platelet unit, if available.

LifeStream provides final results and interpretation to all facilities that have transfused a unit implicated as possibly contaminated.

Depending on product availability, we also use pathogen reduction technology (Intercept Blood System for Platelets--Cerus) on some of our platelet units as stipulated by the December 2020 FDA guidance.

Reference:

Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion: Guidance for Industry, December 2020. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bacterial-risk-control-strategies-blood-collection-establishments-and-transfusion-services-enhance>