IMPORTANT INFORMATION

For blood services customers of Versiti

Blood Services UPDATE

Mitigation of Bacterial Contamination Risk in Platelet Components

November 10, 2021

Versiti discontinued production of conventional bacterial tested platelets in September to meet the requirements of FDA Guidance *Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion* by the Oct 1st deadline. As such we would like to provide an updated memo that documents Versiti's current bacterial testing mitigation strategies that can be used to meet AABB standard requirement 5.1.5.1 or CAP checklist item TRM.44955.

Versiti methods to reduce the risk of bacterial contamination in platelet components:

- **Bacterial Tested Platelets – Large Volume Delayed Sampling**
  - Aerobic and anaerobic sampling (8ml each) 36 hours after collection for 5 day expiration and 48 hours after collection for 7 day expiration
  - Sampling is from each produced adult dose platelet component from a donation
  - Components are released after ≥ 12 hour negative reading
  - Monitored throughout their shelf life, a positive result may be reported after issue and component(s) immediately recalled
- **Pathogen Reduction (PR) Platelets**
  - Pathogen Reduction performed within 24 hours of collection for 5 day expiration

If any of the above testing has not been completed, emergency release sign off will be required.

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