LifeShare
BLOOD CENTER

April 14, 2017

From: Medical and Laboratory Services

Subject: Detection of Bacteria in Leukoreduced Apheresis Platelets

Recommendations and standards established by the Food and Drug Administration and AABB provide directives for preventing and detecting bacterial contamination in Leukoreduced Apheresis Platelets:


"Bacterial contamination testing should be performed using a cultured based methodology, ..."

Standards for Blood Banks and Transfusion Services, AABB, 30th Edition (effective April 1, 2016)

5.1.5 – Aseptic methods shall be employed to minimize the risk of microbial contamination of blood and blood components.

5.1.5.1 – The EB/TS shall have methods to limit introduction of bacteria into the collection.

5.1.5.2 – The EB/TS shall have methods to detect bacteria...

5.1.5.2.1 – Detection methods shall either be cleared or approved by the FDA ... or validated to provide sensitivity equivalent to FDA ... -approved methods.

The following methods are incorporated into LifeShare's processes and procedures to ensure compliance with FDA and AABB recommendations and standards. These methods are audited by FDA and AABB during periodic inspections and assessments:

Aseptic techniques are utilized during collection and all manufacturing steps to limit exposure to bacteria.

Diversion pouches are incorporated into the collection process to limit bacterial contamination of platelet and blood products.

Bacterial testing is performed using a bioMerieux BacT/ALERT Microbial Detection System. This system was approved by the FDA for detecting bacterial contamination in leukoreduced apheresis platelets on December 27, 2005.

Medical facilities will be notified immediately if bacterial testing on a product in their inventory indicates an initial positive result. If the product was transfused prior to notification, results of any confirmatory/identification testing will also be provided.

Please contact your local LifeShare Blood Center facility if you have any questions or require additional information regarding prevention and detection of bacterial contamination in leukoreduced apheresis platelet products.

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