Process Design for Monitoring Microbial Contamination in Cord Blood Products

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To comply with regulatory standards, bacterial and fungal cultures are performed on cord blood harvests manufactured at the St. Louis Cord Blood Bank. A 0.5 ml sample of the final processed product is inoculated into a BacT/Alert aerobic FAN culture bottle (Biomerieux) and 10 ml of the RBC/plasma mixture generated during processing is inoculated into each an aerobic FAN and a standard anaerobic bottle. All are incubated for 7 days. Because the manufacturer indicates that this system does not support the growth of filamentous fungus, 1.5 ml of the RBC/plasma mixture is inoculated into a Pediatric isolator tube (Wampole Laboratories) for fungal cultures.

Examining 3142 cord blood products from September 2001 through December 2003, culture results were considered “clinically relevant” when two or more bottles grew the same organism within 24-36 hours. Results were correlated with contaminated colony forming unit assays and evidence for infection in the donor record. A single positive culture bottle represents a “laboratory contaminant”. The overall rate of positive culture results was 3.3% but only 1.4% were “clinically relevant”. When culture-positive products classified as “laboratory contaminants” are tested post-thaw, the results have been uniformly negative. No evidence for fungal pathogens was demonstrated.

Review of donor records indicates that clinically relevant infection is extremely rare. Although subclinical bacteremia is a contributing factor, positive cultures not classified as contaminants indicate bacteria introduced during collection or processing. In light of these results, incubation of FAN bottles will be extended to 14 days and the use of isolator tubes will be eliminated. Criteria established to distinguish “clinically relevant” culture results from “laboratory contaminants” have been defined. A microbial surveillance scheme must be designed and validated at each bank to identify contamination and prevent discarding valuable cord blood products.