

# Bacti 2011

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SEABB

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Advancing Transfusion and  
Cellular Therapies Worldwide

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# BBTS STD 5.1.5.1

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- The blood bank or transfusion service shall have methods to limit and to detect or inactivate bacteria in all platelet components. Standard 5.6.2 applies.
- 5.1.5.1 shall be implemented by March 1, 2004



# BBTS STD Interim Standard

## 5.1.5.1.1

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- Detection methods shall either be approved by FDA or validated to provide sensitivity equivalent to FDA-approved methods.
- Effective January 31, 2011



# Challenges to Solving Bacterial Contamination

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- Frequency of occurrence
- “At risk “ Patient population
- Detection of bacteria at donation
- Standard test for detection



# Platelet Usage

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**2003** Mixture of apheresis and whole blood derived (WBD)  
Both leukocyte-reduced and not leukocyte-reduced.

**2007** 17% Whole Blood Derived (WBD)



# Testing Methods

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- Apheresis Leukocyte Reduced  
BacT/Alert
- Whole Blood Derived –NLD  
pH  
Glucose  
Microscopic staining



# FDA Concerns

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- Test performance characteristics unknown
- Use of non-validated tests
- Non-standardized methodology
- Potential for excessive false positives
- Two tiered safety system for apheresis and WBD platelets



# January 31, 2011

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- Interim Standard 5.1.5.1.1
- Eliminated the test using
  - pH
  - glucose
  - microscopic reading





# Available Test

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## Leukocyte Reduced

- BacT/Alert: Apheresis–
- Pall Bacteria Detection System(BDS) Apheresis & WBD
- Pall Acridose PL System WBD
- Verax Biomedical's PGD Test Apheresis & WBD
  - Not Leukocyte-Reduced
- Pall Acridose Plus System WBD
- Verax Biomedical's PGD test Apheresis & WBD



# Third Option

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- Your creative method
- Not FDA Approved
- Validated sensitivity and specificity
- Review at accreditation assessment



# Things To Remember

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- Positive Test Results
- Agreements
- Emergency Release Plan



# Standards Questions

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- Policy states we only transfuse cultured platelets. If we get uncultured platelets on weekends, then pool them, and issue them under emergency release, is this acceptable?
- Using the Pall eBDS, we would sample the pooled platelets, issue them, then incubate the pouch for 18-30 hours. The results would be available a day or two after transfusion. Would this meet the standard?



# Information & Discussion

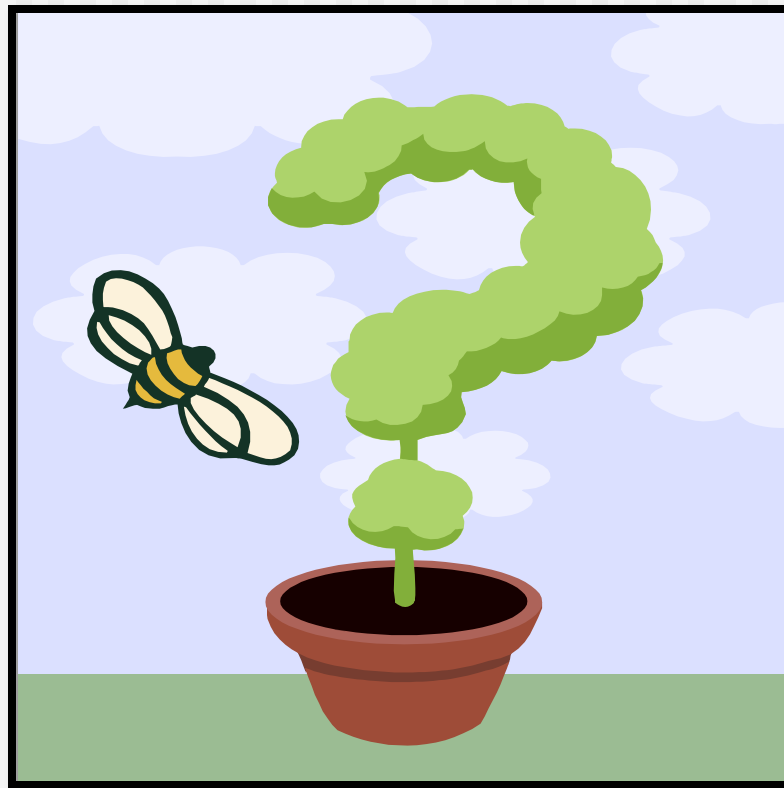
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- The AABB Blood Bank & transfusion Service Standard Program Unit has initiated a discussion thread in the Standards and Quality Group.
- [www.aabb.org](http://www.aabb.org); Enter AABB Community, Find a Group, Standard and Quality Group





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