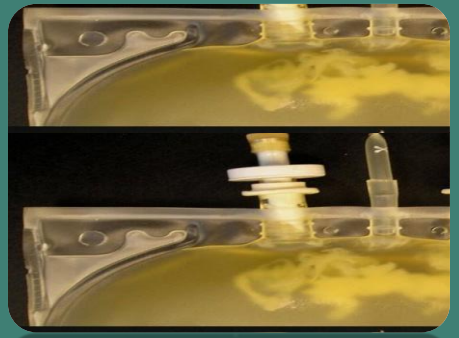
Bacterial Contamination in Platelets

Canadian Blood Services - Update



Sandra Ramirez-Arcos

ISBT TTID WP Meeting

June 17, 2017

Canadian Blood Services

it's in you to give

Bacterial testing –automated BacT/ALERT® 3D culture system

Routine Platelet Screening	Quality Control Sterility Testing
Screening of 100% platelet products	Screening of 1% products (minimum 10 units) on a monthly basis
Screening is done 24 to 30 hours post-collection	Screening is done at outdate (6-7 day old platelets)
Sampling: 8 and 10 mL of PCs inoculated into aerobic culture bottles	Sampling: 8 and 10 mL of PCs inoculated into aerobic and anaerobic culture bottles
Incubation in the BacT/ALERT® 3D system for a maximum of 6 days	Incubation in the BacT/ALERT® 3D system for a maximum of 6 days
Once sampling is performed and other tests are completed, platelets are put into inventory	Once sampling is performed and other tests are completed, platelets are discarded
➢ Bacterial screening of PCs at CBS is not a pre-release test	

Confirmed positive cultures – Routine platelet screening (2010-2016)

PC Component (N)	Species identified	
	Gram positive bacteria (N)	Gram negative bacteria (N)
Apheresis PCs (18 out of 186,737) Rate/10,000 = 0.96	CoNS (1) *Streptococcus spp* (8) *Corynebacterium spp* (1) *Bacillus* (1) *Enterococcus faecium* (1)	*Escherichia coli* (3) *Serratia marcescens* (3)
Buffy coat pooled PCs (57 out of 601,988 tested) Rate/10,000 = 0.94	CoNS (33) *Streptococcus spp* (9) *Bacillus spp* (5) *Staphylococcus aureus* (4) *Actinomyces* (1) *Enterococcus faecium* (1)	*Morganella morganii* (1) *Serratia marcescens* (1) *Pseudomonas aeruginosa* (1) *Citrobacter koseri* (1)

Residual risk

- Bacteria captured in outdated products (2010-2016)- 0.8-0.9/1,000 - All Gram positive bacteria
- Transfusion reactions with platelets that tested negative: 554,666 platelets transfused (2010 –2016):
  - Rate septic transfusion reactions ~ 1/100,000
  - Rate fatalities ~ 1/500,000
  - All Gram positive bacteria

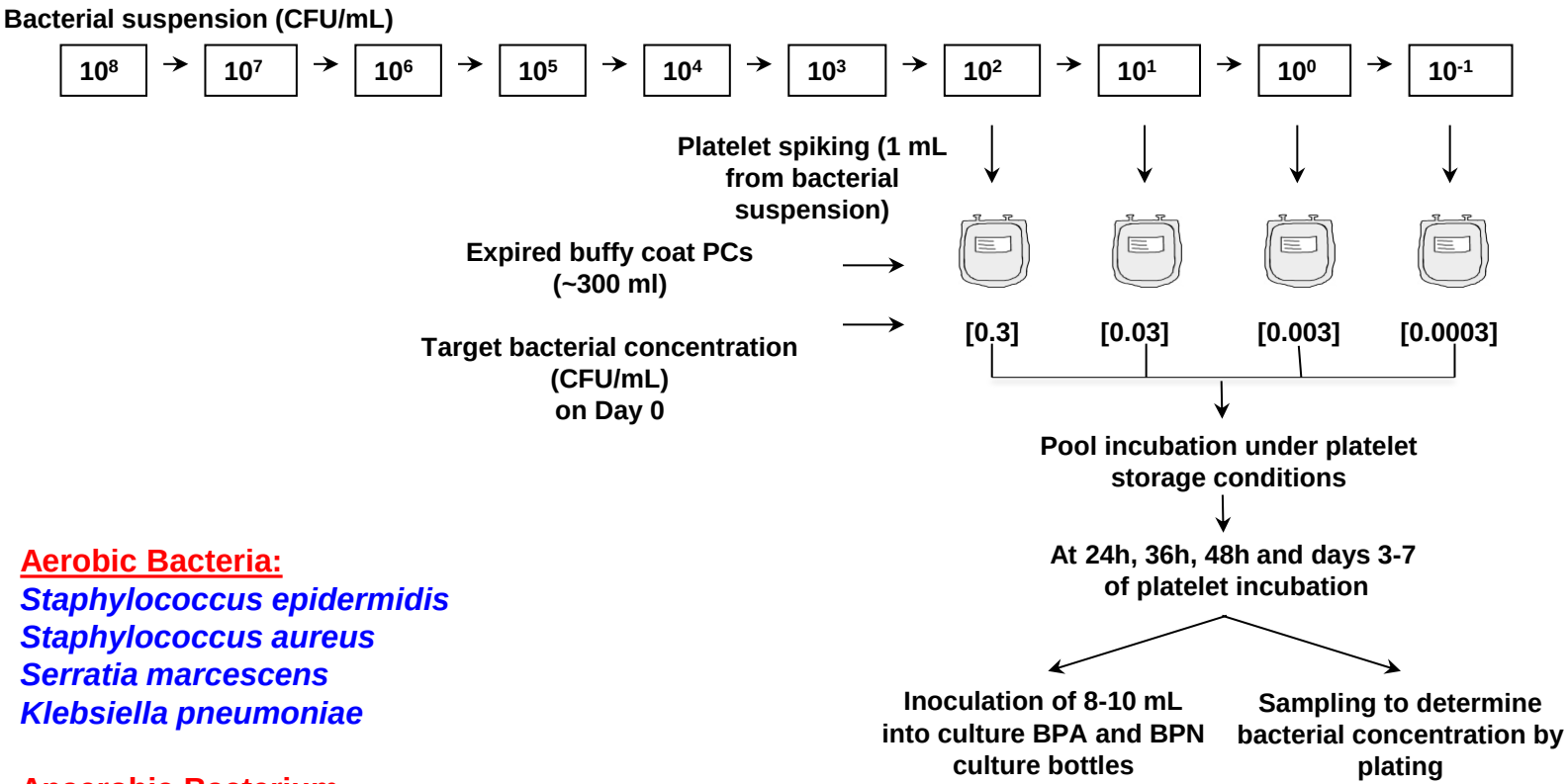
Date	Component	PC age (days)	Organism
2010-03	buffy coat	5	Coagulase negative *Staphylococcus*
2010-07	apheresis	5	Coagulase negative *Staphylococcus*
2011-11	buffy coat	5	*Staphylococcus aureus*
2012-01	apheresis	3	*Staphylococcus aureus*
2014-09	buffy coat	5	*Staphylococcus epidermidis* (fatal)
2016-05	buffy coat	4	*Staphylococcus aureus*

Ramirez-Arcos et al. Transfusion 2017, *In press*

Extending platelet storage with new testing algorithm

	Current	Upcoming
Sampling time post-collection	**24 -30**	**≥ 36 h**
Volume	**8-10 ml**	**16-20 ml (40 ml for double apheresis)**
Bottles	**Only aerobic**	**Aerobic and anaerobic**
Post-inoculation quarantine	**None**	**≥ 6 h**

Spiking study to test the new algorithm - Protocol



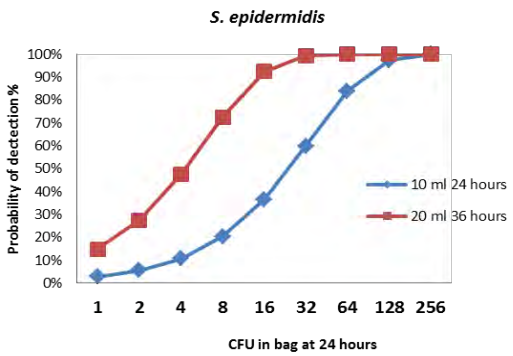
Aerobic Bacteria:

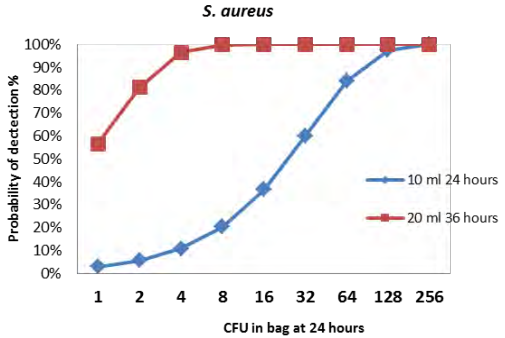
Staphylococcus epidermidis
Staphylococcus aureus
Serratia marcescens
Klebsiella pneumoniae

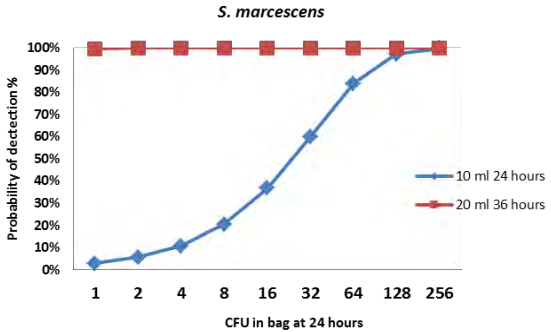
Anaerobic Bacterium:

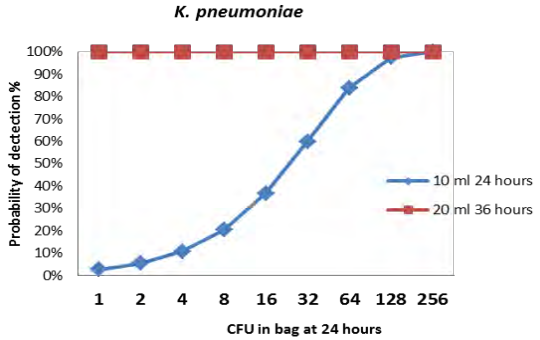
Propionibacterium acnes

Spiking study to test the new algorithm - Results









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What about pathogen inactivation?

Pathogen inactivation and biofilms

S. epidermidis 10^6 CFU/ml

Biofilm

OR

Non-biofilm

Whole blood

Buffy coat manufacturing

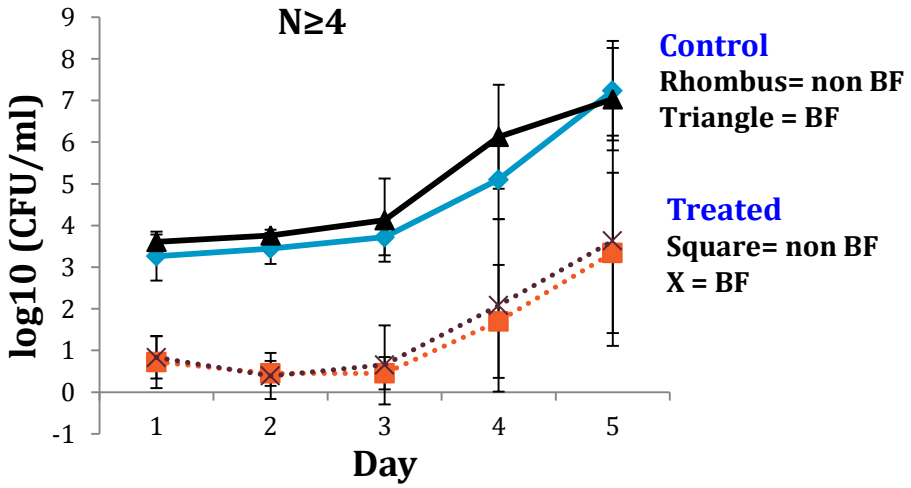
UV treated

*

Riboflavin +

10^3 CFU/ml of bacteria

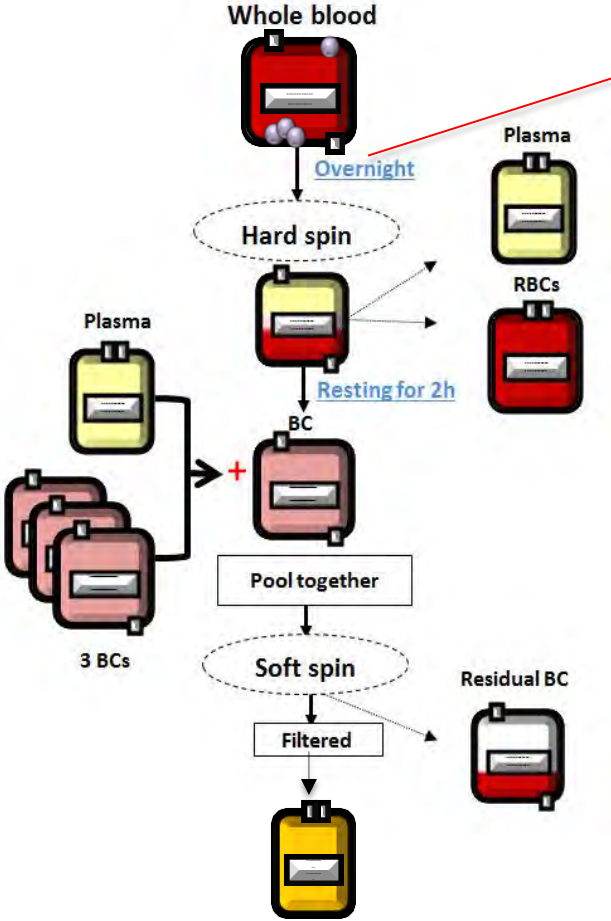
Control

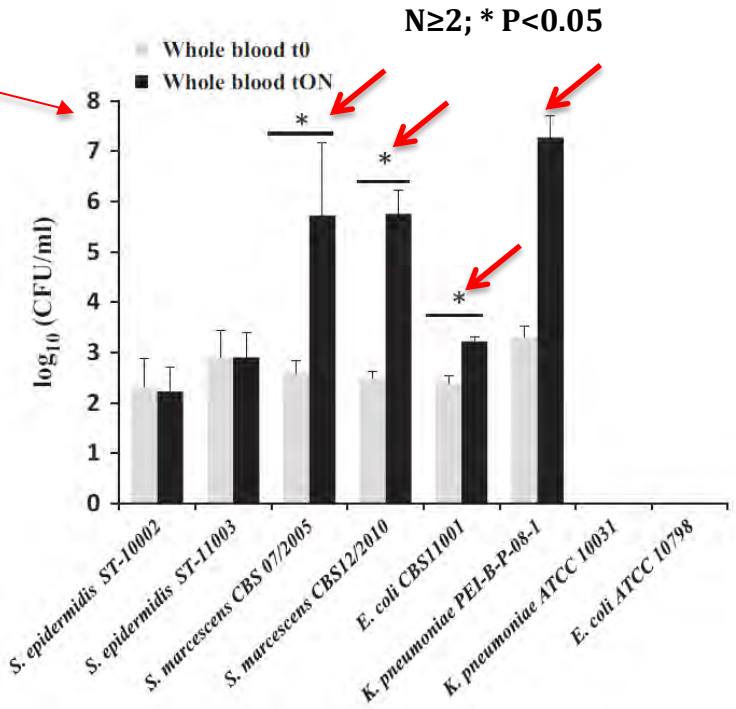


Visit poster P252

Taha et al Vox Sanguinis 2017 Apr 5. doi: 10.1111/vox.12519

BC-PC production





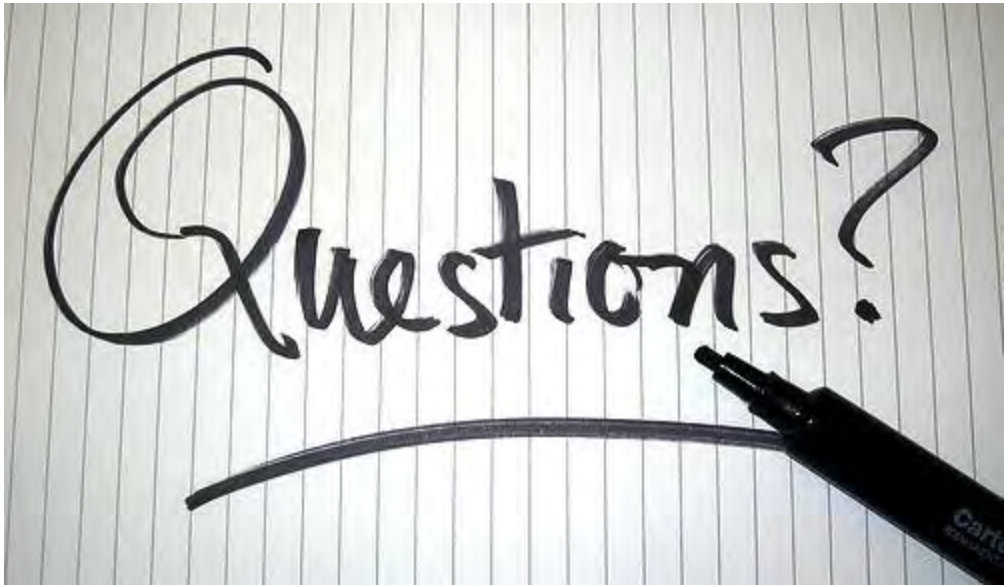
Taha et al, Vox Sanguin 2016, DOI: 10.1111/vox. 12427

Summary

- **Platelet screening for bacterial contamination has had a positive impact on safety, likely preventing transfusion reactions**

- **Missed detection during routine platelet screening is evidenced during sterility testing of expired platelets and septic transfusion reactions**

- **Measures to enhance platelet safety**
  - ***Improving testing algorithm with 7day platelets – delay sampling***
  - ***Pathogen inactivation?***
  - ***Testing at the hospital end with a rapid method?***


Questions?

Breakout Session Bacteria Subgroup - Agenda

Topic	Presenter
Platelet storage medium and transfusion transmitted bacterial infections	Aukje Kreuger, Sanquin Research, Leiden
Rapid Detection of Bacterial Contaminants in Platelet Components: Comparison of Time to Detection between the BacT/ALERT® 3D and the BacT/ALERT ® VIRTUO™ Systems	Parampal Deol, bioMérieux
Update on the ISBT TTID study on establishment of bacterial reference strains for RBCs	Marcel Prax, Paul-Ehrlich Institute
Mirasol System for Whole Blood: Update on Bacterial Reduction and Development Plan	Heather Pidcoke, TerumoBCT
Bacteria inactivation capacity of the THERAFLEX UV-Platelets system: systematic investigation using the WHO Bacteria Reference Strains	Alex Seltsam, German Red Cross
Bacterial inactivation claims in the context of sterility. A follow up on the NBL PI validation study with the INTERCEPT system	Adonis Stassinopoulos, Cerus
Discussion – Potential collaborative studies, new initiatives	All

THANK YOU