

KNOWLEDGE INFUSION: FOCUS ON AABB 2016

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Truly innovative: non-destructive quality assessment of platelet concentrates in mini bags

*Prepared by Canadian Blood Services Knowledge Mobilization Team
with special thanks to Peter Schubert*



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Welcome to

KNOWLEDGE INFUSION: FOCUS ON AABB 2016

AABB 16 ORLANDO

The Event Advancing Transfusion and Cellular Therapy

**MEETING: OCTOBER 22-25, 2016
EXHIBITION: OCTOBER 22-25, 2016
ORANGE COUNTY CONVENTION CENTER**

KnowledgeInfusion
SPOTLIGHT ON AABB 2016



CENTRE FOR INNOVATION PRESENTS



Name: **Peter Schubert**

Title: **Research Associate, Centre for Innovation**

Location: **Centre for Blood Research, Vancouver, BC**

Presentation Learning Objectives:

- ✓ **By the end of the session, participants will be able to describe non-destructive quality assessment of platelets and its importance to Canadian Blood Services.**



Truly innovative:
non-destructive quality
assessment of platelet
concentrates in mini-bags



- **Peter Schubert**
- C4I Knowledge Infusion
- 2017-02-02



patients trust that the products we provide will be safe and effective throughout their shelf life



we routinely check product quality at expiry as part of our QC program



Table 3
Allergic blood component quality control in manufacturing
(See Clauses 7.4.2, 7.5.1.3, 7.7.1, and 7.13.1)

Note: The parameters and tests in this Table are intended for manufacturing quality control in large-scale production for components pooled pre-transfusion in hospitals.

Component	Test (time of sampling)	Specification	Frequency* (sample)	Quantity of units to be tested each month	
Plasma, pooled (see annex 1, e.g., Buffy coat method)	Plasma yield (at any time)	Greater than or equal to 2 x 10 ⁸ (unit)	In at least 70% of units tested (unit or segment) ¹	2% of production, minimum 10	
	pH (post-expression)	6.4-7.8	In at least 50% of units tested (unit or segment) ¹	2% of production, minimum 10	
	Residual white blood cell counts after leukoreduction (within 48 h after leukoreduction)	Less than 5 x 10 ⁶ / mL (unit)	In all units tested (unit or segment) ¹	2% of production, minimum 10	
	Identify (post-expression)	No growth	In all units tested (unit or segment) ¹	2% of production, minimum 10	
Plateletpheresis	Plasma yield (at any time)	Greater than or equal to 2 x 10 ⁸ (unit)	In at least 70% of units tested (unit or segment) ¹	2% of production, minimum 10	
	pH (post-expression)	6.4-7.8	In at least 50% of units tested (unit or segment) ¹	2% of production, minimum 10	
	Residual white blood cell counts after leukoreduction (within 48 h after leukoreduction)	Less than 5 x 10 ⁶ / mL (unit)	In all units tested (segment) ¹	2% of production, minimum 10	
	Identify (post-expression)	No growth	In all units tested (unit or segment) ¹	2% of production, minimum 10	
All blood components produced with a sterile connecting device (post-expression)				No growth	In all units tested (unit or segment) ¹

* Number of components required to meet specification for the purpose to be considered in control.
¹ Segment shall be made at time of sampling indicated in this Table, not at time of component preparation.
 † This conditional or real blood cells may be combined with those conducted in plasma for purposes of determining compliance with a

but testing at expiry means that products selected for QC end up...



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what if ?

- you could take a small sample from a unit
- store that small sample to expiry
- and the quality attributes of that small sample were representative of the unit

then

you could return the sampled unit to inventory, and QC becomes *non-destructive* !

Canadian Blood Services
Société canadienne du sang

Jan. 8, 2016

Dr. Dana Devine
Chief Medical and Scientific Officer

Dear Dana,

I want to share my expectations for your performance in 2016-2017. For us to achieve our vision, we need your commitment and leadership in our fiscal year performance plans and operational annual plans and

product	number of units used for QC testing 2012-13	direct cost per unit used 2012-13	total direct cost of product used for QC testing 2012-13
apheresis platelets	1249	\$478	\$597,022
buffy coat derived pooled platelets	1216	\$165	\$200,640

...regarding the feasibility of non-destructive testing for the organization.

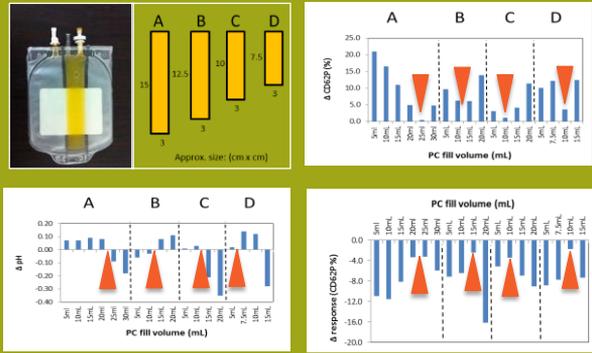
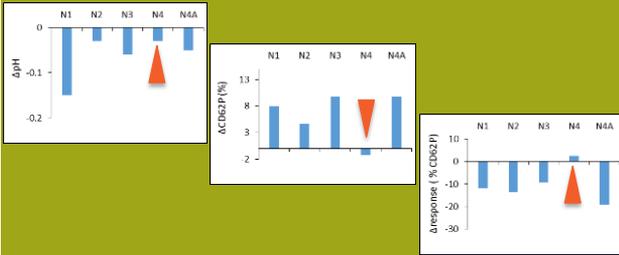
your commitment,

Graham



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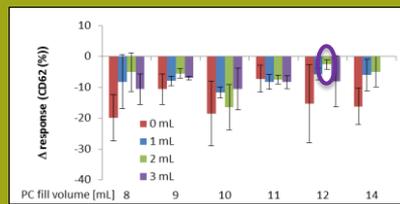
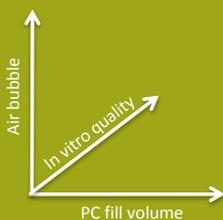
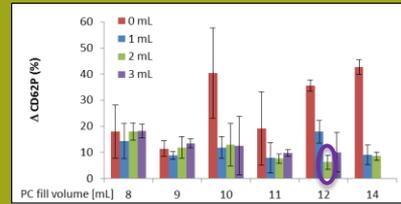
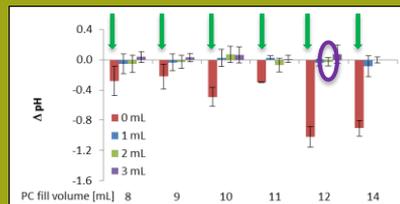
start with an idea...



platelet quality is dependent on the shape/size and fill volume of the segment.



see what might be feasible...



→ Quality in mini-bags is dependent on an air bubble.
 → P17 with 12 mL fill volume and 2 mL air bubble demonstrated best configuration.



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thank
you!

 **Centre for Innovation**

