

# The quality of platelet concentrates with pathogen inactivation treatment using INTERCEPT Blood System

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# Introduction

- Bacterial risk reduction technologies to reduce TTI
- INTERCEPT Blood System
- Amotosalen hydrochloride and UV-A illumination
- Permanent bonds in nucleic acids
- Study impact of PI on the quality of NHSBT platelet concentrates (PC)

## **Effect of PI on platelet components under standard conditions**

- Apheresis platelet concentrates (in Plasma using Trima)
- Apheresis neonatal splits
- Washed apheresis PC (SSP and SSP+)
- Buffy coat derived PC (8 pooled BC developed\*)

## **Effect of PI under conditions of natural variations in collection and distribution**

- High concentration apheresis platelet concentrates
- Worst case transport/agitation conditions

## pH at expiry – under standard conditions

- Studies are pool and split with 2 arms

	<b>Control Non Treated</b>	<b>INTERCEPT Treated</b>
Apheresis PC (Day 7)	7.25 (7.14-7.36)	6.95 (6.82-7.08)
Neonatal PC (Day 7)	7.05 (6.96-7.14)	6.84 (6.68-7.00)
BC Derived PC (Day 7)	7.43 (7.39-7.49)	7.29 (7.10-7.37)
Washed PC SSP (24hr)	6.73 (6.61-6.93)	6.72 (6.58-6.93)
Washed PC SSP+ (24hr)	7.22 (7.20-7.25)	7.19 (7.16-7.21)

n=6 showing Mean (Min and Max)

- Specification - pH at end of shelf life  $\geq 6.4$  (95% components tested)
- All PC above the minimum specification

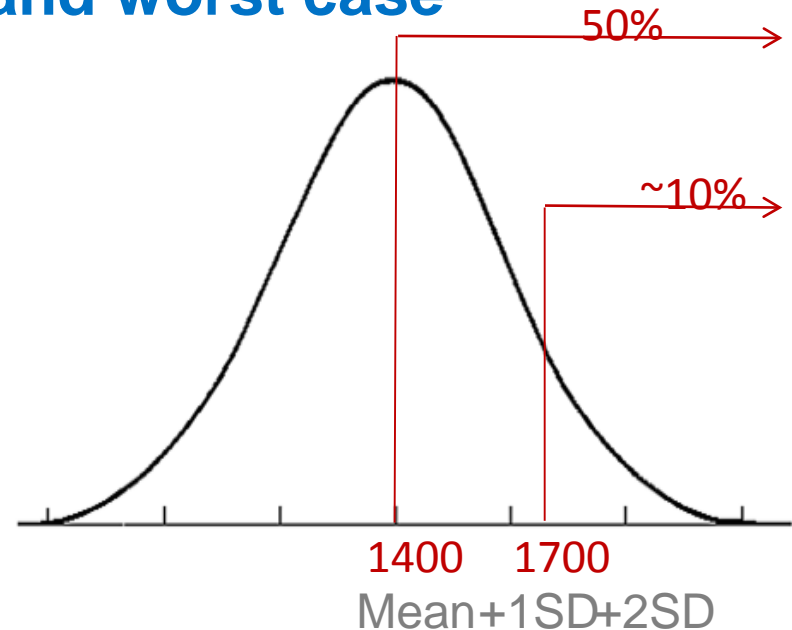
## High platelet concentrations and worst case transport/agitation

- **Concentrations**

- Normal concentration  
 $1400 \times 10^3/\mu\text{L}$
- High concentration  
 $1700 \times 10^3/\mu\text{L}$

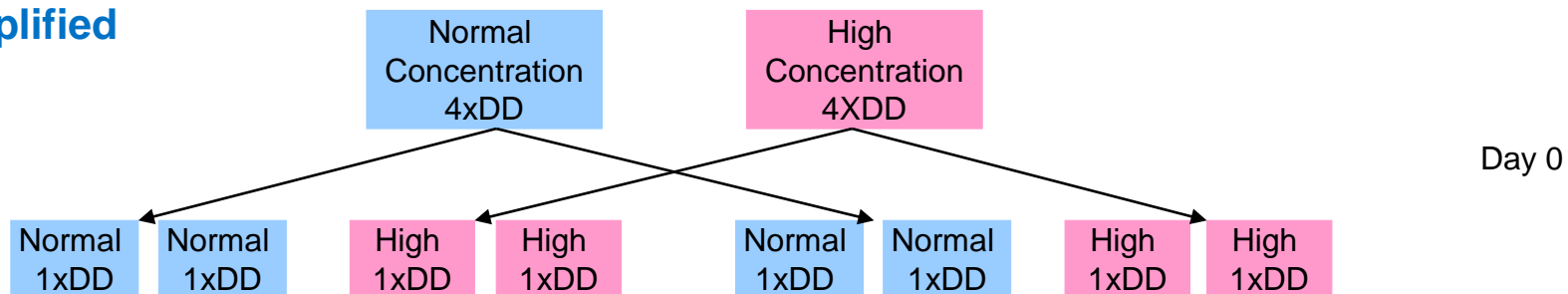
- **Transport/no agitation**

- NHSBT transport bags
- Wrapped in a plastic bag (standard procedure)
- Guidelines – No longer than 24 hrs, no single period of more than 8 hours
  - Worst case - 3 periods of 8 hours
  - Good/Normal - 4 periods of 2 hours



# Study Design

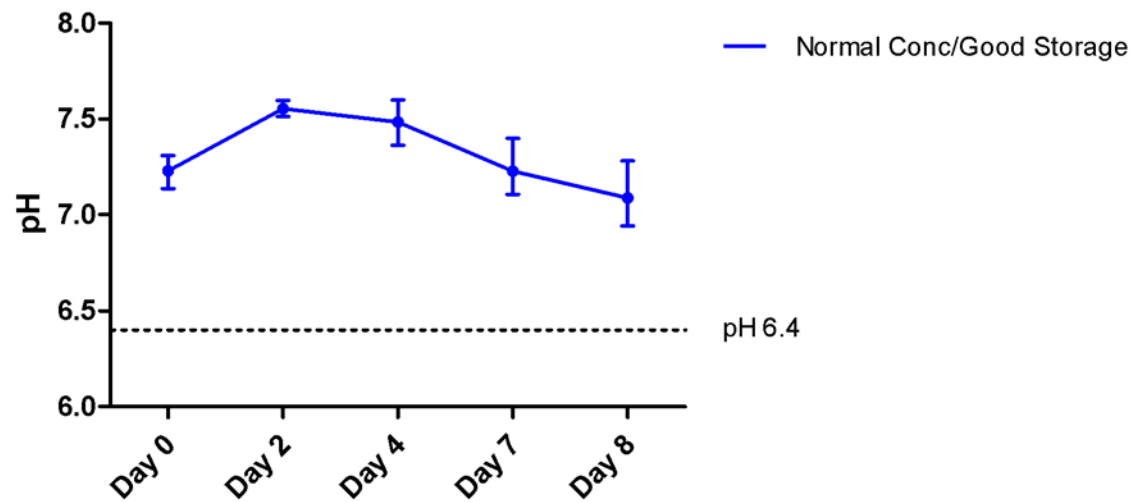
Simplified



n=6

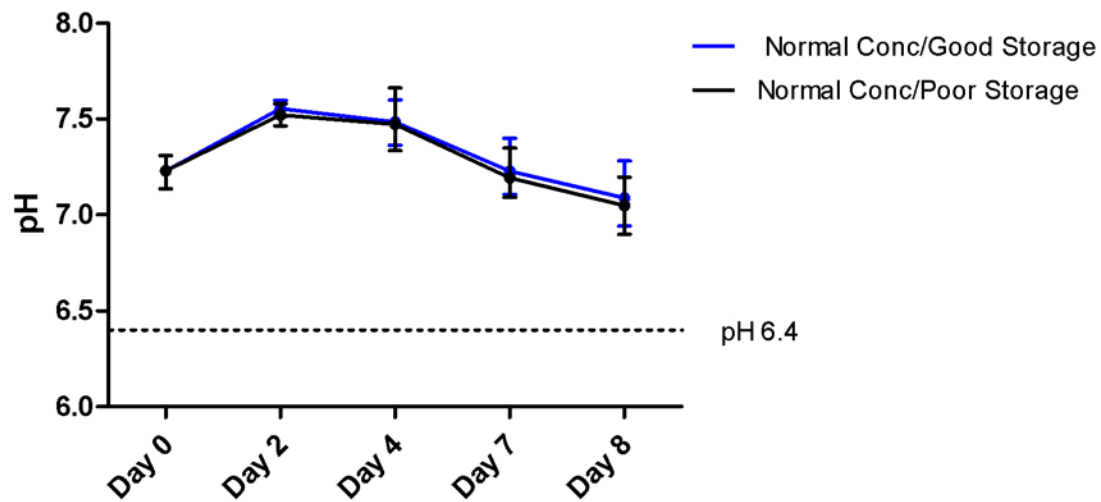
Sent for bacterial screening at end of storage

# pH during storage - no PI treatment



n=6 mean (min-max)

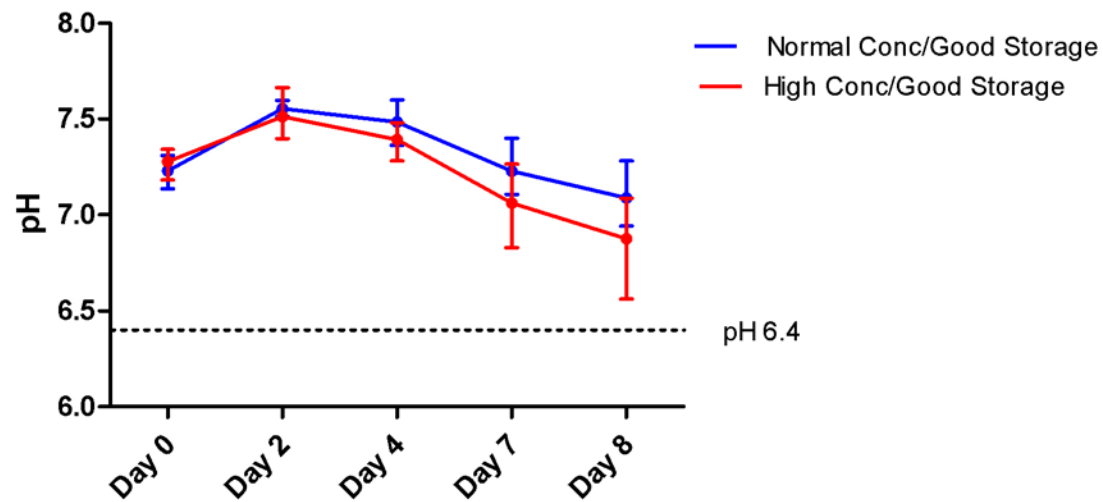
# pH during storage - no PI treatment



n=6 mean (min-max)

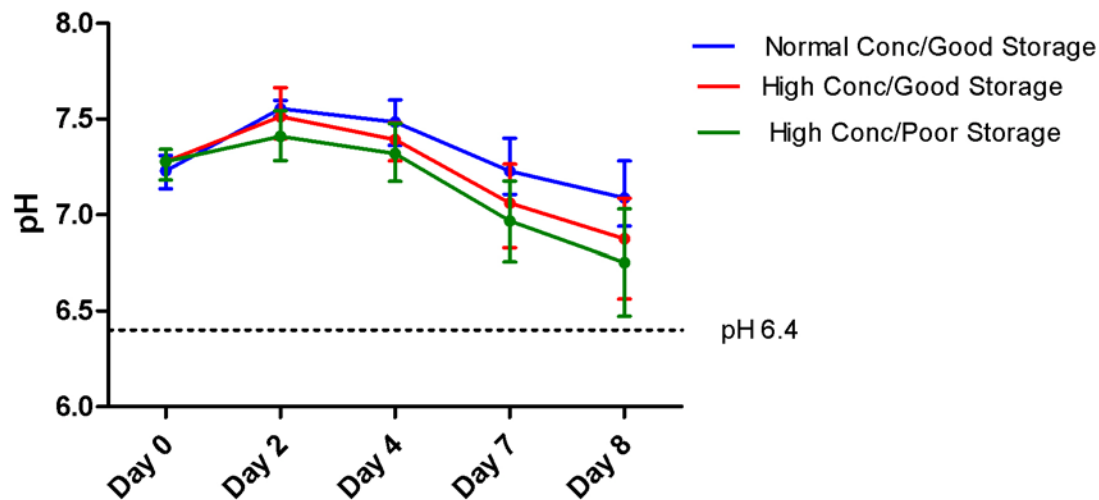


# pH during storage - no PI treatment



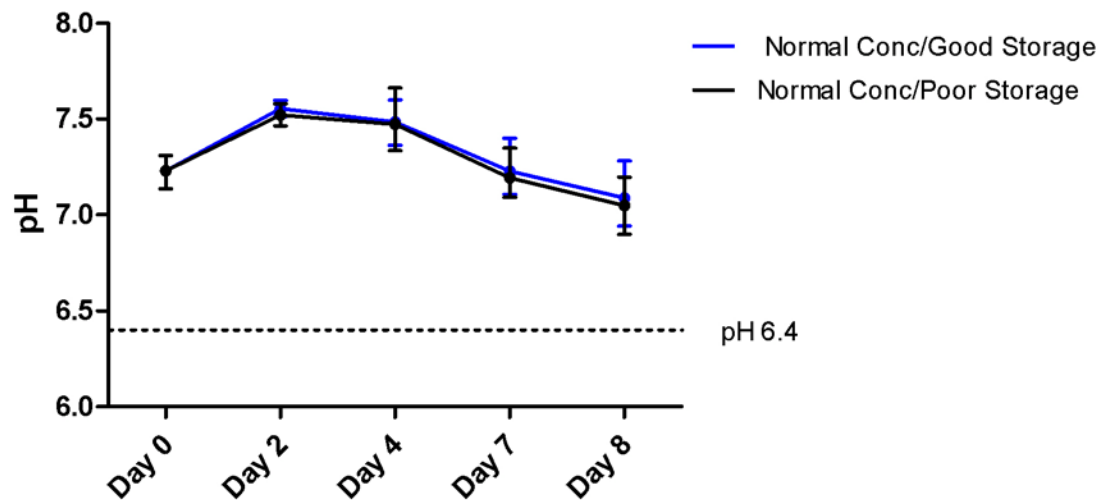
n=6 mean (min-max)

# pH during storage - no PI treatment



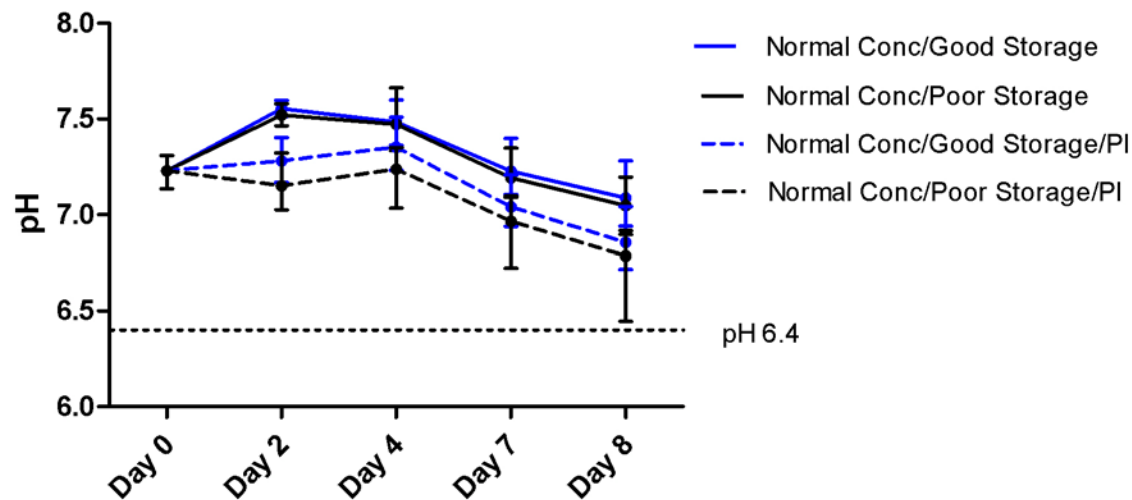
- Specification - pH at end of shelf life  $\geq 6.4$  (95% components tested)
- All PC above the minimum specification

# pH during storage – normal concentration with PI treatment



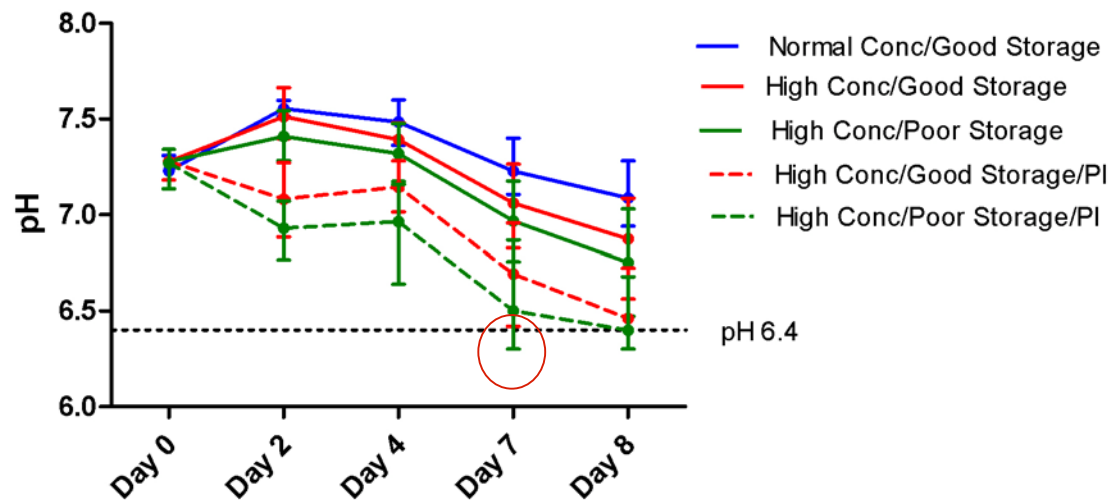
n=6 mean (min-max)

# pH during storage – normal concentration with PI treatment

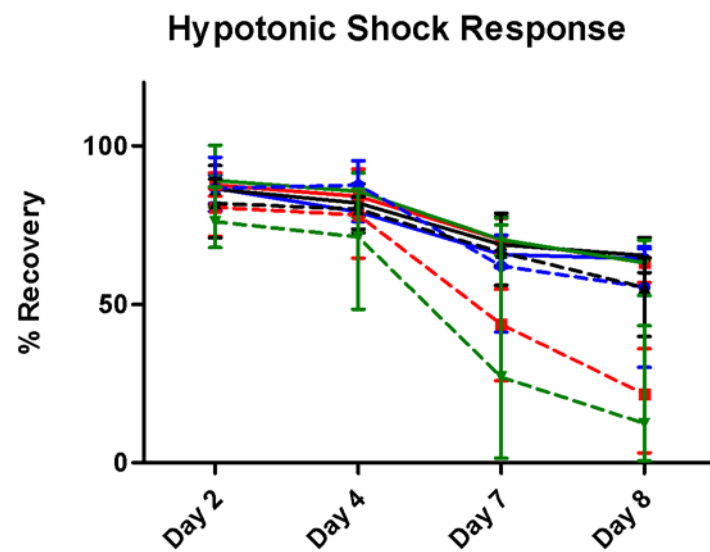
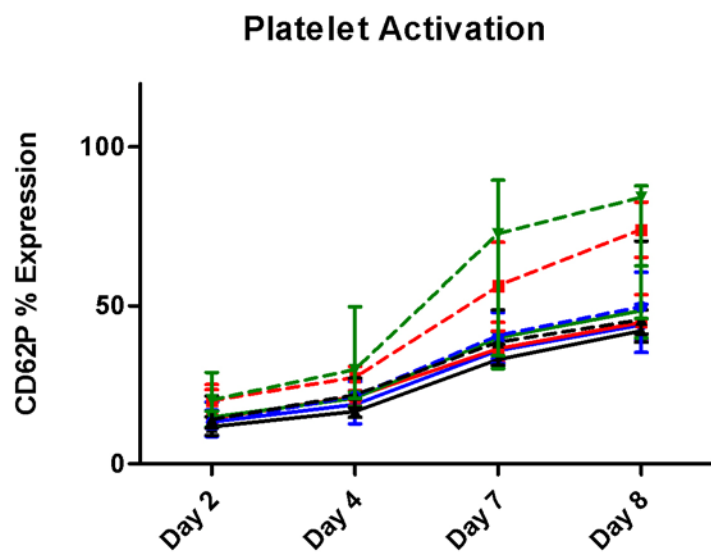
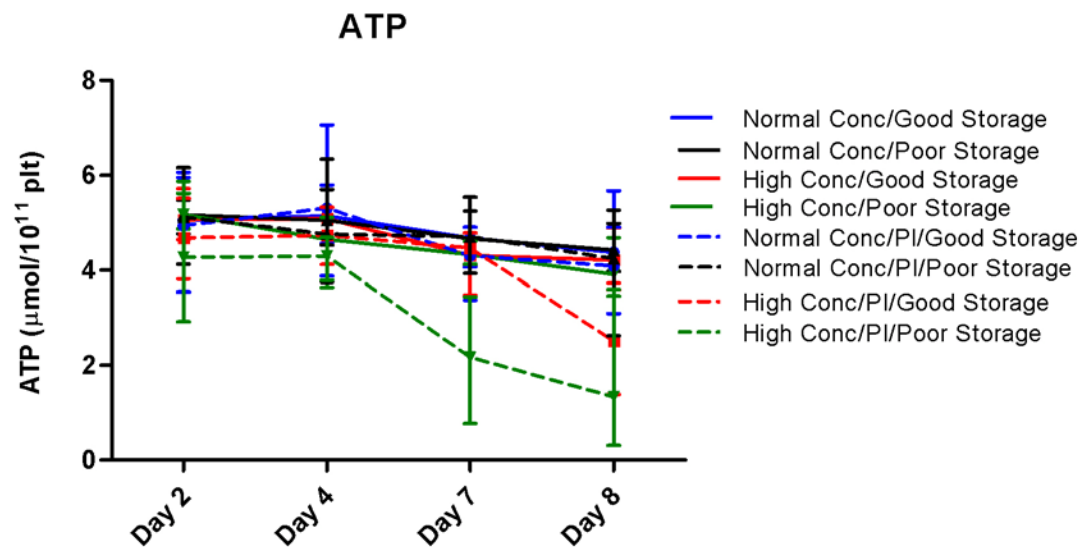


n=6 mean (min-max)

## pH during storage – high concentration with PI treatment



- At Day 7 - 3 of the 6 PI treated high concentration/poor storage  $\text{pH} \leq 6.4$



# Conclusions

- pH is well maintained in all the INTERCEPT treated components under standard conditions
  - supported by other test parameters
- High platelet concentration has greater impact on the quality than poor transport/agitation
  - when combined with INTERCEPT treatment there is potential for pH failures
  - impacts on small numbers of PC with high platelet concentration that have also undergone poor transport

## Potential solutions

- Use larger volume storage container (Cerus)
- Apheresis platelets in additive solution
- Reduce the variation in platelet concentration
  - on the day platelet counts
- Reduce shelf life
- Investigate the effect of plastic wrapping platelets in transport
- **Important** – This study looked at Worst Case transport, not actual NHSBT conditions



# Many Thanks

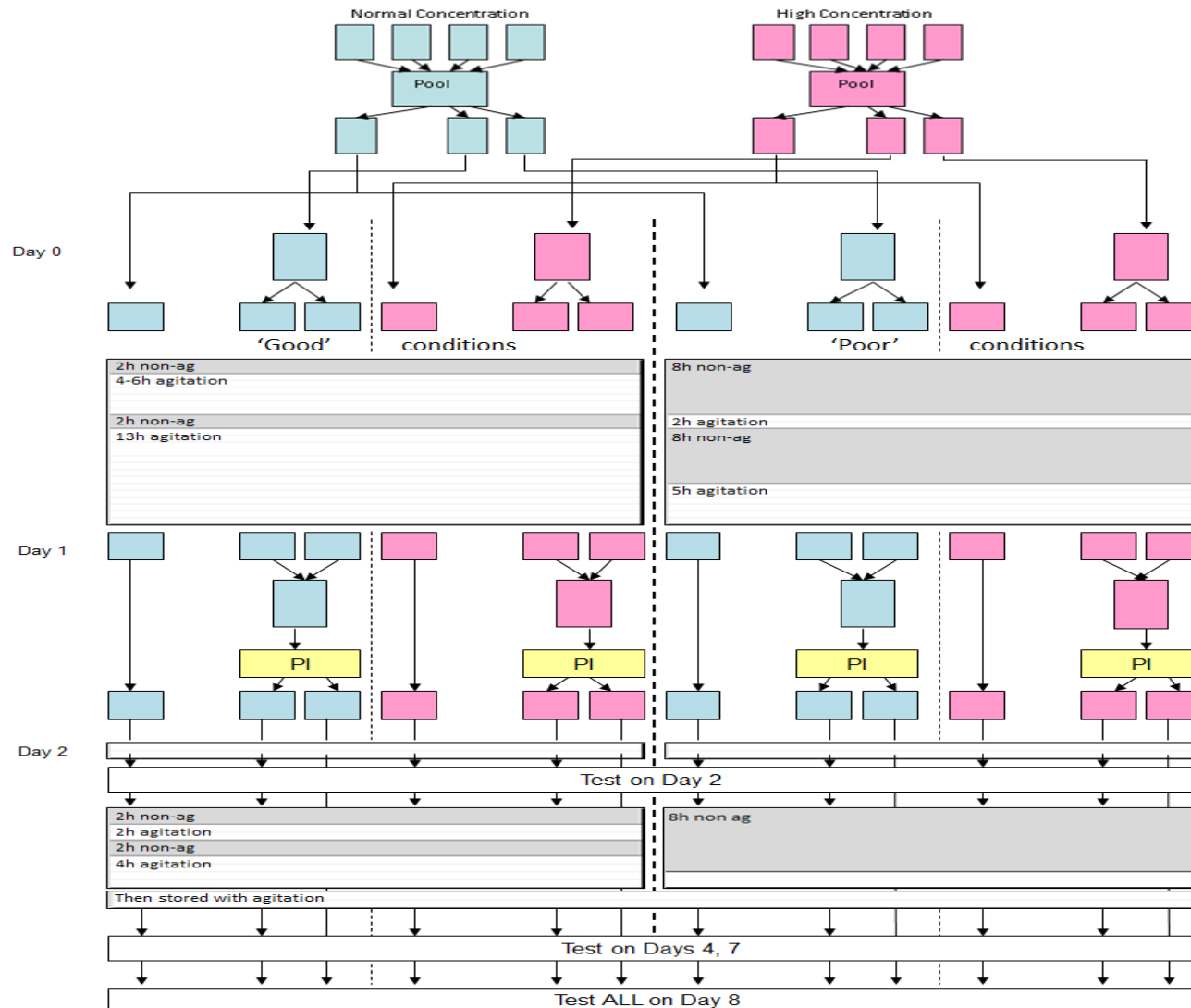


- Wonderful Donors
- My colleagues in NHSBT
  - Component Development Laboratory, Cambridge
  - Blood Donation Clinic and Alan Blakeman, Cambridge
  - Hospital Services, Cambridge and Filton
  - Manufacturing and Hospital Services, Filton
  - National Bacteriology Laboratory, Colindale
  - Donna Blair, Donation Technology
- Also
  - Alan Cole, Terumo
  - Nick Moerman, Cerus

**Any Questions?**



# STUDY DESIGN



# Platelet Concentrate Characteristics

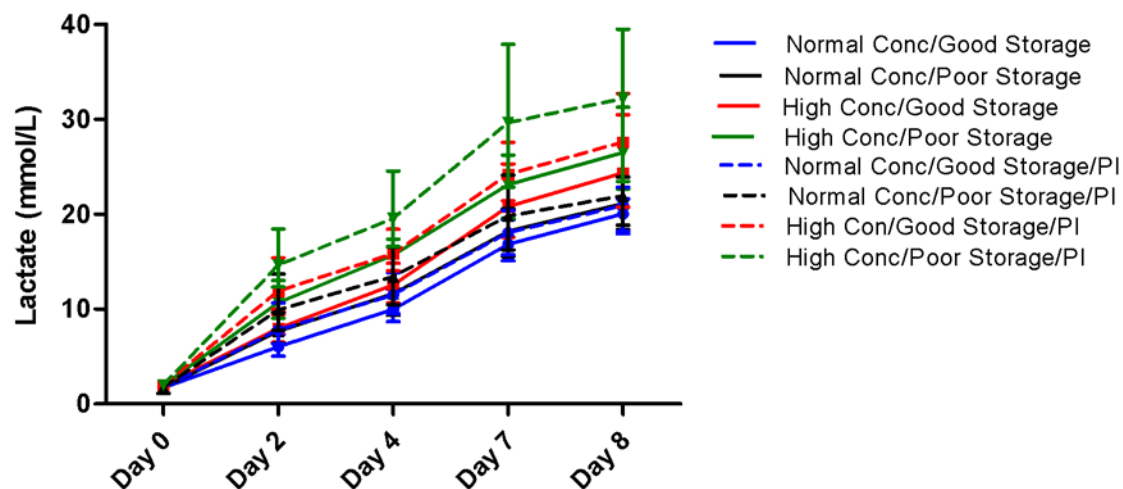
## Pre INTERCEPT Treatment

	Mean	Minimum	Maximum
Concentration x10 <sup>9</sup> /L	1412	1264	1580
(Normal)			
Concentration x10 <sup>9</sup> /L	1660	1538	1850
(High)			
Volume mL	417.90	415.92	419.51
Yield Plts x10 <sup>11</sup> /unit	5.92	5.30	6.63
(Normal)			
Yield Plts x10 <sup>11</sup> /unit	6.96	6.43	7.73
(High)			

## Cerus Guardbands

Platelet Count x10 <sup>11</sup> /unit	Volume mL
2.5-7.0	300-420
7.1-8.0	375-420

# Lactate and Glucose



n=6 mean (min-max)

At Day 7 glucose was undetectable in one high conc/poor storage/PI treated

