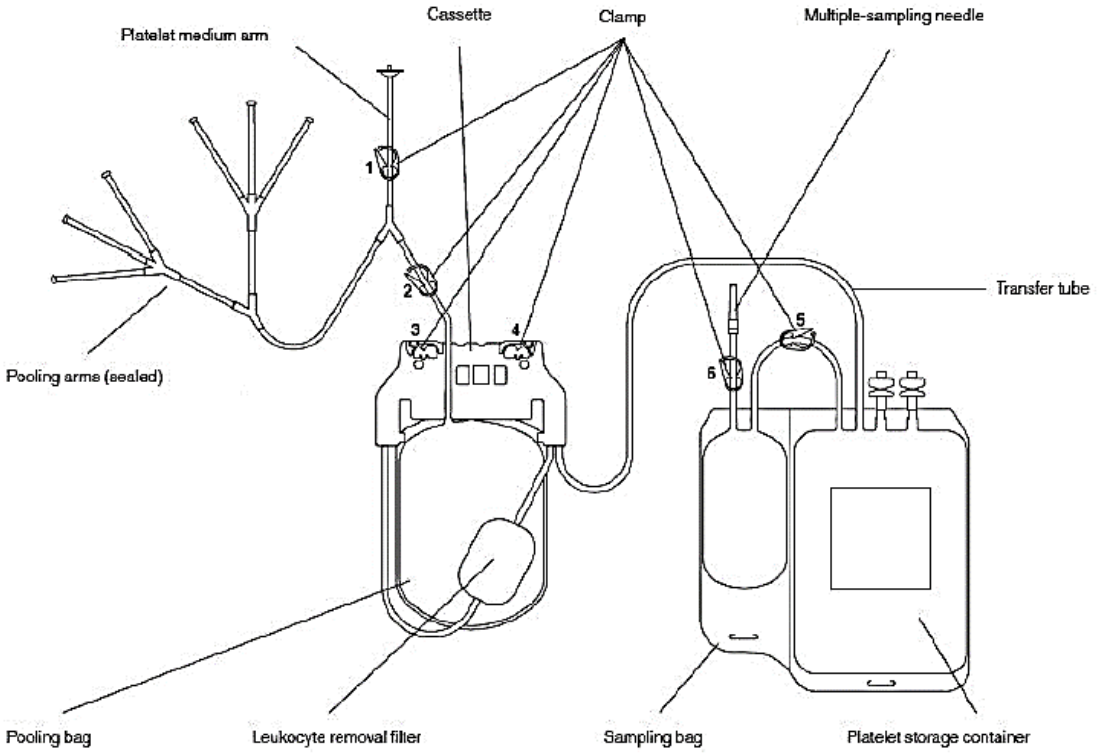
TACSI PL – THE WELSH EXPERIENCE

Christine Saunders

TERUMO AUTOMATED CENTRIFUGE AND SEPARATOR INTEGRATION (TACSI) system

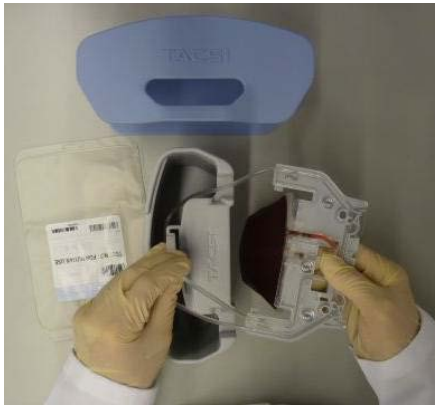
- PLATELET (PL) SYSTEM
  - Manufacture of platelet concentrates (PCs) from pooled buffy coats
- WHOLE BLOOD (WB) SYSTEM
  - Process whole blood into red cell concentrates, plasma and buffy coats
  - AND manufacture of PCs from buffy coats
  - (as 2 separate processes)

TACSI PL KIT



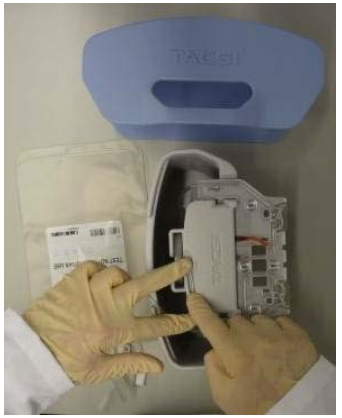
Item	Designation
1	Insert cover
2	Insert
3	Filter holder
4	Tube guide
5	Cassette fixation holes

TACSI PL OPERATION



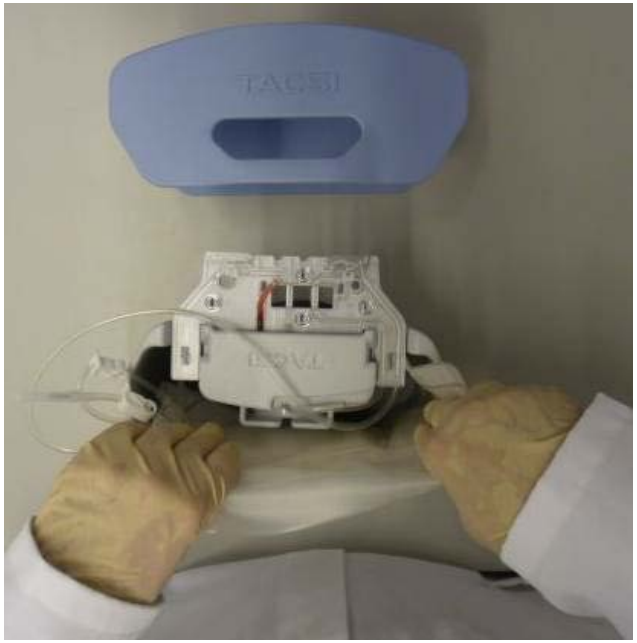
Place the filter in the filter holder

Hook the cassette into the insert and then push until a click is heard



Insert the tubing into the tube guide

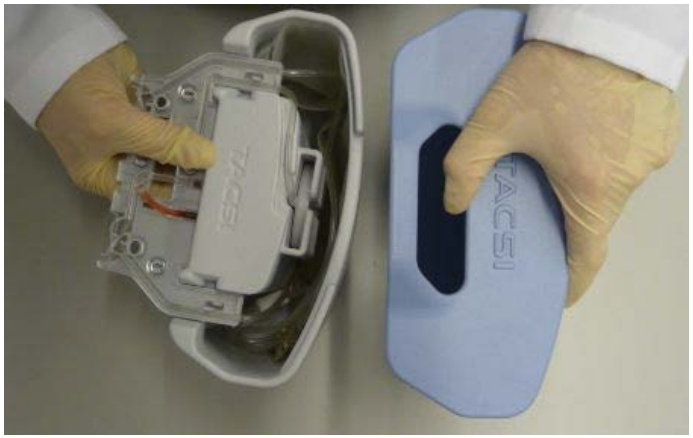
TACSI PL OPERATION



Slide the storage pack into the insert, with the outlet ports on the left.

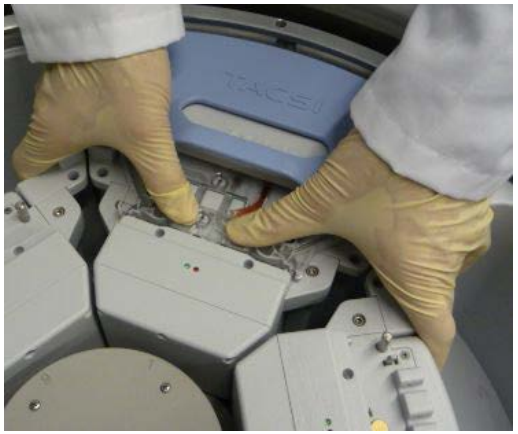
Push the tubing into the insert

TACSI PL OPERATION

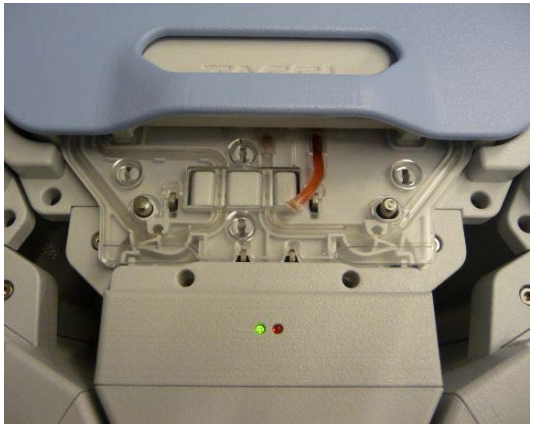


Lift the insert and slot into the cover

Place the insert into a system box

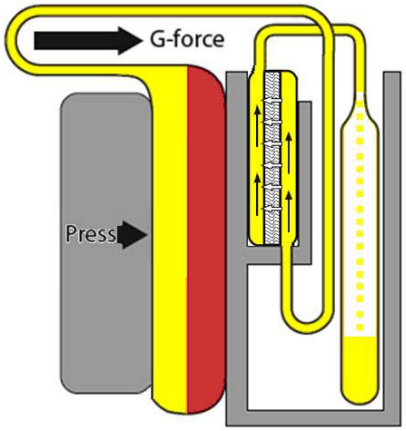


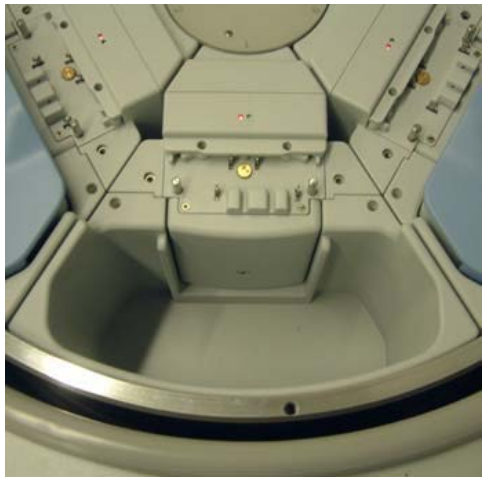
Lock the insert by pushing down on the middle of the cassette until a click heard

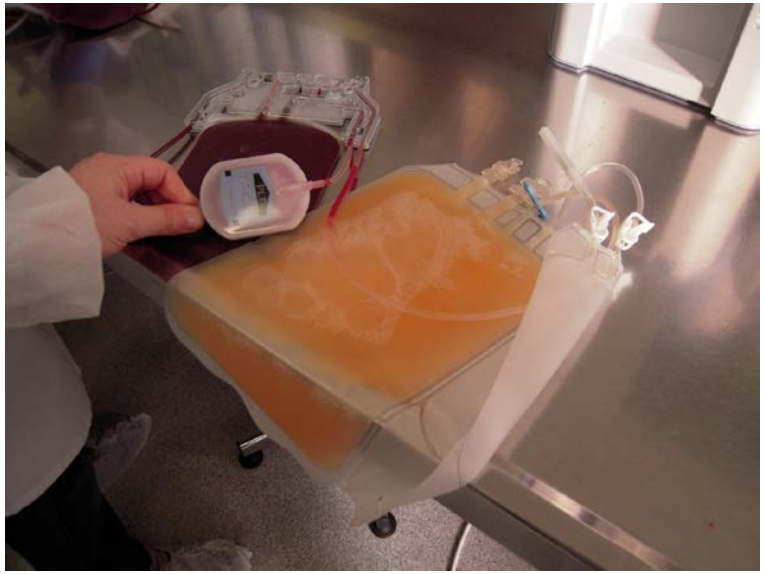


A green light confirms the insert is loaded correctly and the cassette locked

TACSI PL OPERATION







Separation and filtration of the platelet concentrate and configuration of the system box with associated press module

TACSI PL – WBS EVALUATION

- Storage characteristics of PCs manufactured by TACSI PL and stored for 8 days in either 100% autologous plasma or approximately 70% additive solution (T-PAS+)
- 4 buffy coats pooled after overnight hold at 22 ± 2°C. Pool with either unit of plasma or 250 mL T-PAS+
- Parameters tested:
  - Platelet concentration and yield, unit volume, mean platelet volume, swirling, pH, blood gases, glucose consumption and lactate production, hypotonic shock response, extent of shape change, ATP, soluble CD62P levels, surface expression of CD62P and annexin V binding, bacterial screening at end of storage.
- Units tested on days 1, 6 and 8.
- Results compared with manually processed units from 2007/2008 trial.

PC IN 100% AUTOLOGOUS PLASMA

- n = 14

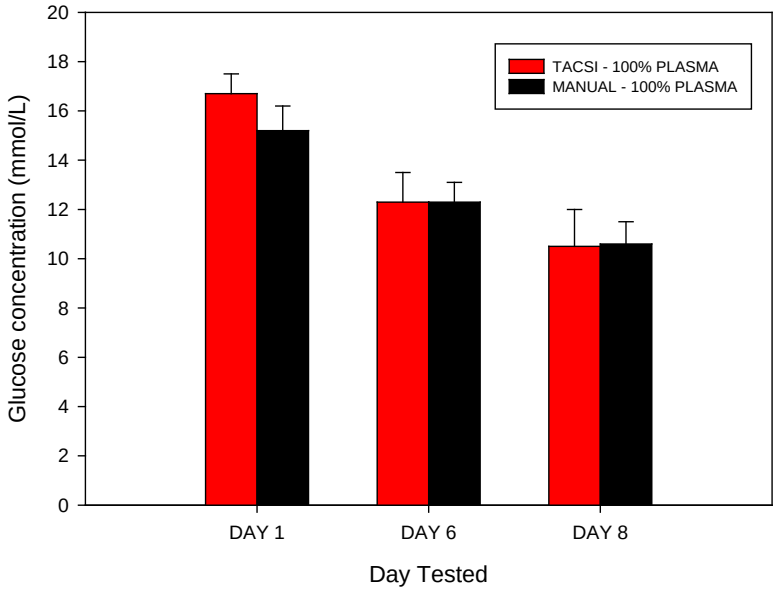
	Volume (mL)		Platelet Yield (x10^9/unit)		Residual WBC Count (x10^6/unit)#
Specification	27.5 mL per 55 × 10^9 plts*		> 240		<1.0
Impact of bacterial monitoring	Before sampling	After sampling	Before sampling	After sampling	[No discernible impact on WBC counts]
Mean	343.0	323.0	403.4	379.8	<0.2
SD	17.1	17.1	45.9	43.5	0.14
Min	307.2	287.2	336.8	316.3	<0.2
Max	369.5	349.5	490.8	461.8	0.34
% meeting specification	100	100	100	100	100

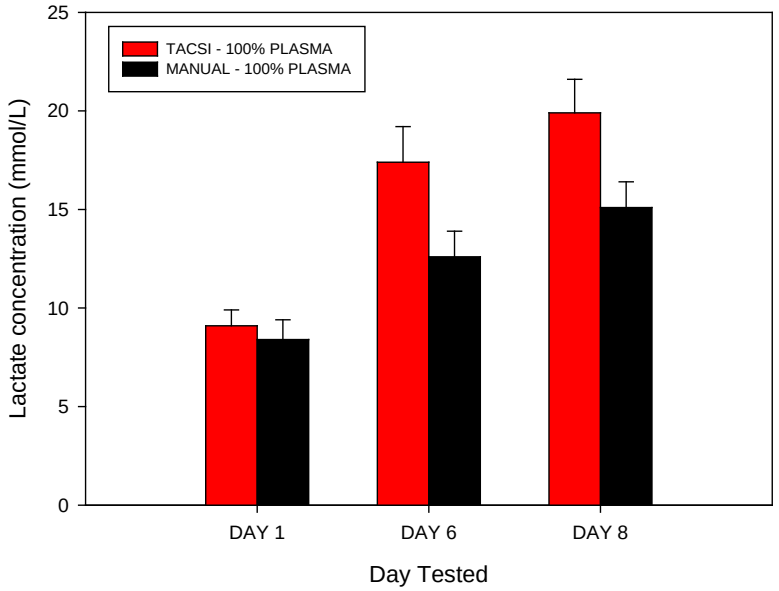
*: Local WBS specification

#: Assay validated to a limit of quantitation of 0.2 × 10^6 WBC/unit

Note: “After sampling” refers to the subtraction of nominal 20 mL volume from the measured value, reflecting volume removed for bacterial monitoring

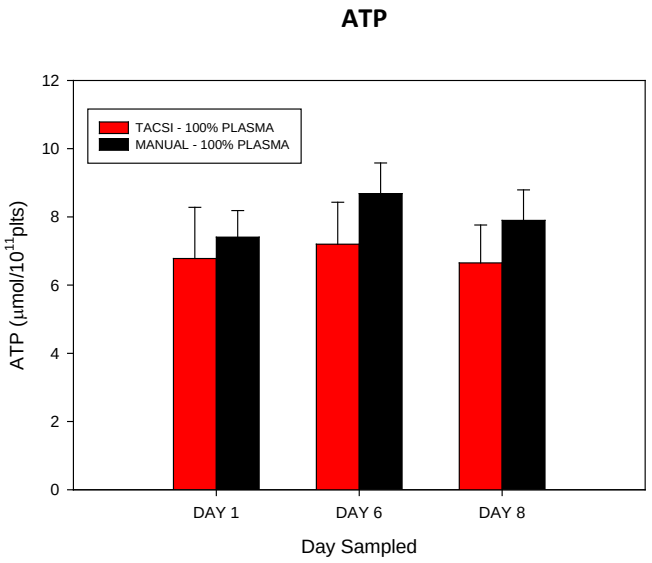
PC IN 100% AUTOLOGOUS PLASMA



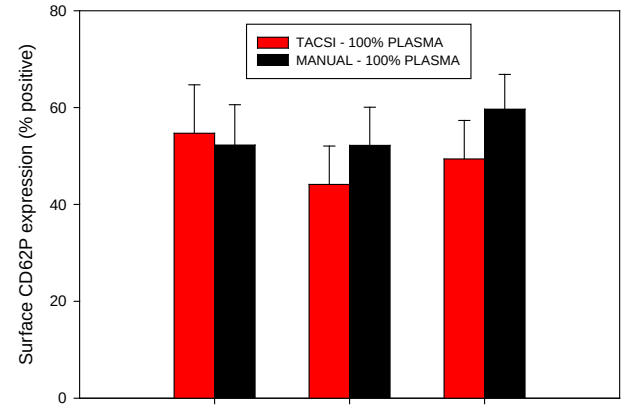


Glucose consumption (mmol/10^{12} platelets/day)		Lactate production (mmol/10^{12} platelets/day)	
TACSI (n=14)	MANUAL (n=13)	TACSI (n=14)	MANUAL (n=13)
0.88	0.65	1.31	0.92

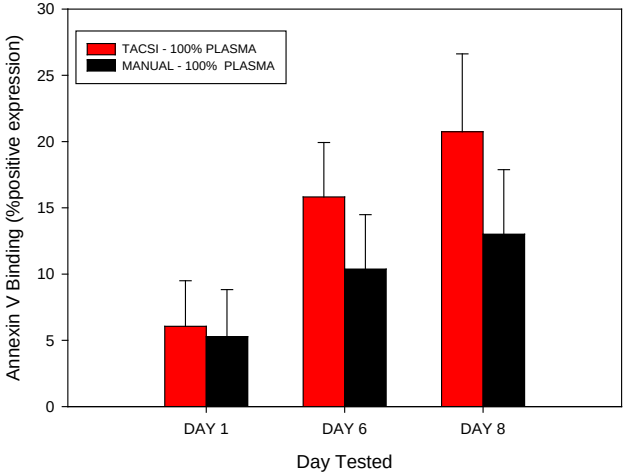
PC IN 100% AUTOLOGOUS PLASMA



- Recommendation to proceed to Phase 1 evaluation.



CD62P (surface expression)



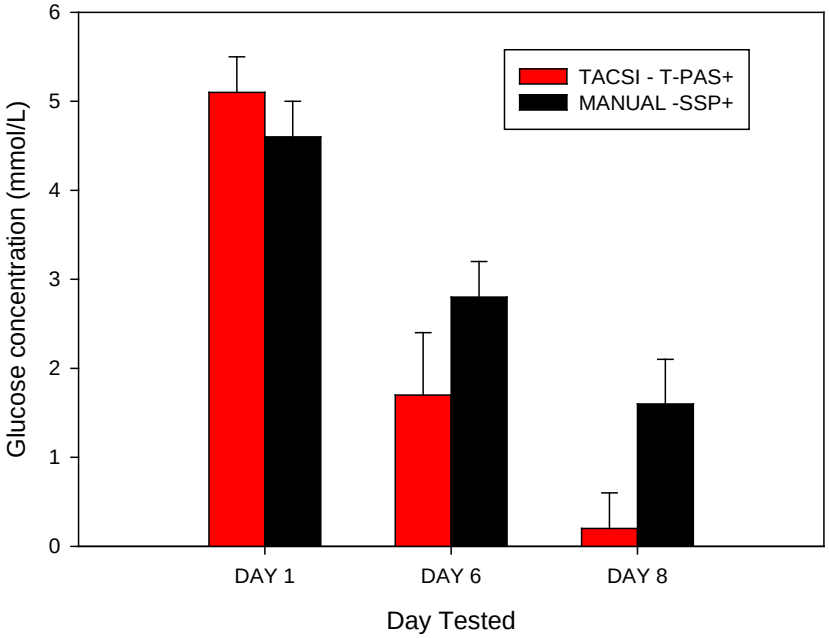
Annexin V Binding

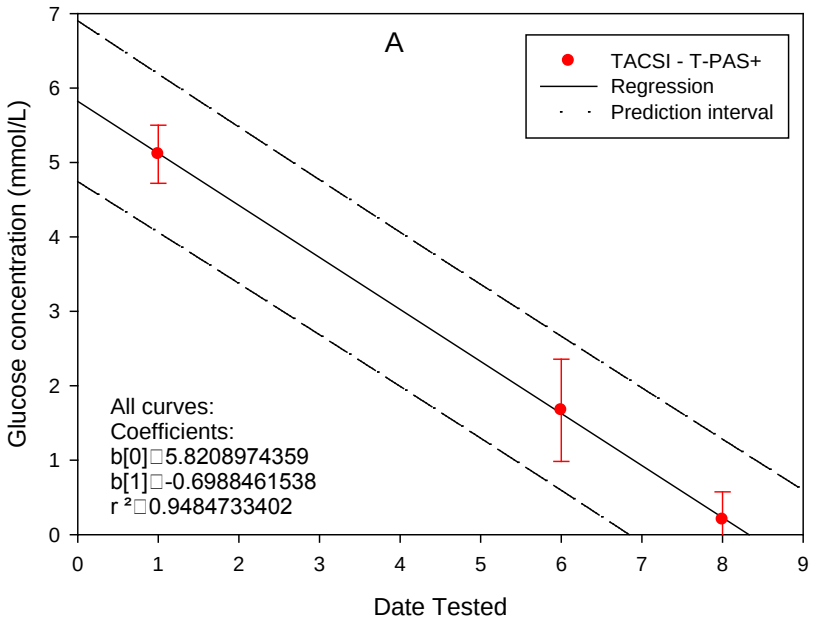
PC IN T-PAS+

	Volume (mL)		Platelet Yield (x10^9/unit)		Residual WBC Count (x10^6/unit)	
Impact of bacterial monitoring	**T-PAS+**	**Plasma**	**T-PAS+**	**Plasma**	**T-PAS+**	**Plasma**
Mean	**282.5**	**323.0**	**318**	**379.8**	**<0.2**	**<0.2**
SD	**11.0**	**17.1**	**39**	**43.5**	**N/A**	**0.14**
Min	**267.5**	**287.2**	**239**	**316.3**	**<0.2**	**<0.2**
Max	**301.6**	**349.5**	**365**	**461.8**	**<0.2**	**0.34**
% meeting specification	**100**	**100**	**90**	**100**	**100**	**100**

- Volumes reflect value after a nominal 20 mL volume was subtracted from the measured volume, reflecting volume loss for bacterial screening.
- Platelet concentration similar in T-PAS+ units and plasma units (1129 ± 162 x 10^9/L versus 1178 ± 136 x 10^9/L, respectively). Difference in yield therefore related to lower unit volume.

PC IN T-PAS+





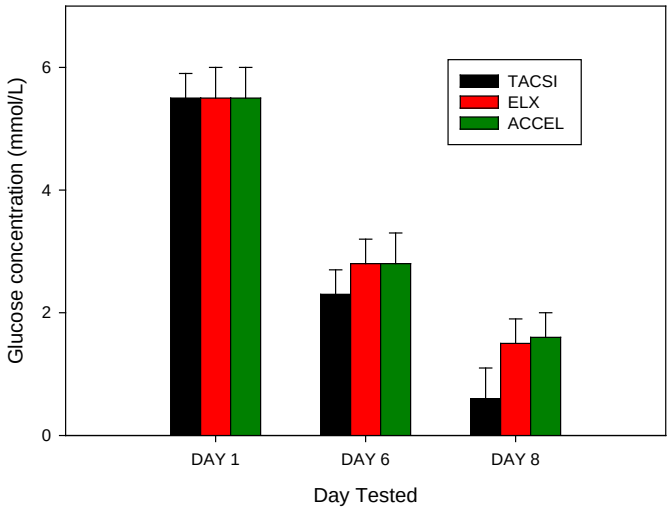
- Mean glucose consumption rate of 0.64 mmol/10^{12}platelets/day compared to manually prepared units in SSP+ (0.44 mmol/10^{12}platelets/day)

WHY IS GLUCOSE BEING CONSUMED AT A FASTER RATE IN TACSI PL UNITS?

- Variables include:
  - Storage conditions – the same
  - Additive solution – SSP+ has the same composition as T-PAS+
  - Storage packs - ??

- Pool and split study. Manufacture three ABO group-specific PC in TACSI system, pool and split into three different storage packs:
  - ELP pack from Trima Accel apheresis collection system (Terumo)
  - ELX pack for buffy coat-derived PC (Haemonetics)
  - TACSI PL storage pack

COMPARISON OF STORAGE PACKS



	Glucose (mmol/L) (n=5)			
	TACSI	ELX	ACCEL	p
DAY 1	5.5 ± 0.5	5.5 ± 0.5	5.5 ± 0.5	0.891
DAY 6	2.3 ± 0.4	2.8 ± 0.4	2.8 ± 0.5	<0.001
DAY 8	0.6 ± 0.5	1.5 ± 0.4	1.6 ± 0.4	<0.001

	TRIMA ACCEL	TACSI PL	ELX
Plastic	BTHC-PVC	BTHC-PVC	Polyolefin
Sterilisation	Ethylene oxide	Ethylene oxide	

IMPRESSIONS OF THE TECHNOLOGY

- STAFF IMPRESSIONS
  - Easy to operate
  - Quiet
  - Efficient
- COMPONENT
  - Consistent component in terms of volume and platelet yield
  - Should have fewer issues with red cell contamination compared to manual processing
  - Effective leucoreduction
- CONCERNS
  - Glucose levels at end of storage

THANK YOU