

Quality assessment of red blood cell concentrates and
plasma units collected in DEHT-PAGGSM or DEHT-SAGM
blood bag devices
European Franco-Belgian study



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Conflict of interest

The study was funded by MacoPharma

Study context

Di(2-ethylhexyl)-phthalate (DEHP) is a common component in blood collection systems

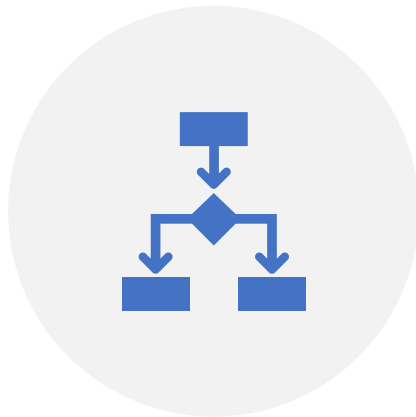
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graph TD; A[Di(2-ethylhexyl)-phthalate (DEHP) is a common component in blood collection systems] --> B[DEHP ban in 2030 (REACH)]; B --> C[Replacement solution: Dioctyl terephthalate (DEHT) plasticizer and phosphate-adenine-glucose-guanosin-saline-mannitol (PAGGSM) additive solution]; C --> D[Collaborative and multiparametric study];
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DEHP ban in 2030 (REACH)

Replacement solution: Dioctyl terephthalate (DEHT) plasticizer and phosphate-adenine-glucose-guanosin-saline-mannitol (PAGGSM) additive solution

Collaborative and multiparametric study

Aim



→ ASSESS DEHT-PAGGSM BAGS
COMPARED TO DEHT-SAGM



→ STORAGE STUDY ON RBCC
AND PLASMA



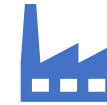
→ REQUIREMENTS: EDQM, 21TH
VERSION

Study design



Whole blood collection at SFS

Processing



16 DEHT-PAGGSM

8 DEHT-PAGGSM

8 RCC

8 plasmas

8 DEHT-SAGM

8 RCC

8 plasmas

8 DEHT-PAGGSM

8 RCC

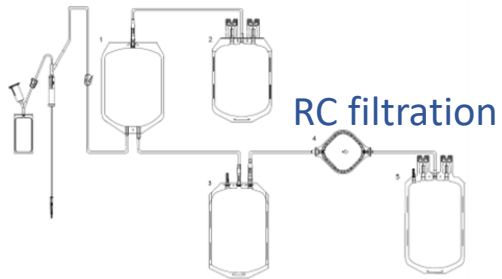
8 plasmas

8 DEHT-SAGM

8 RCC

8 plasmas

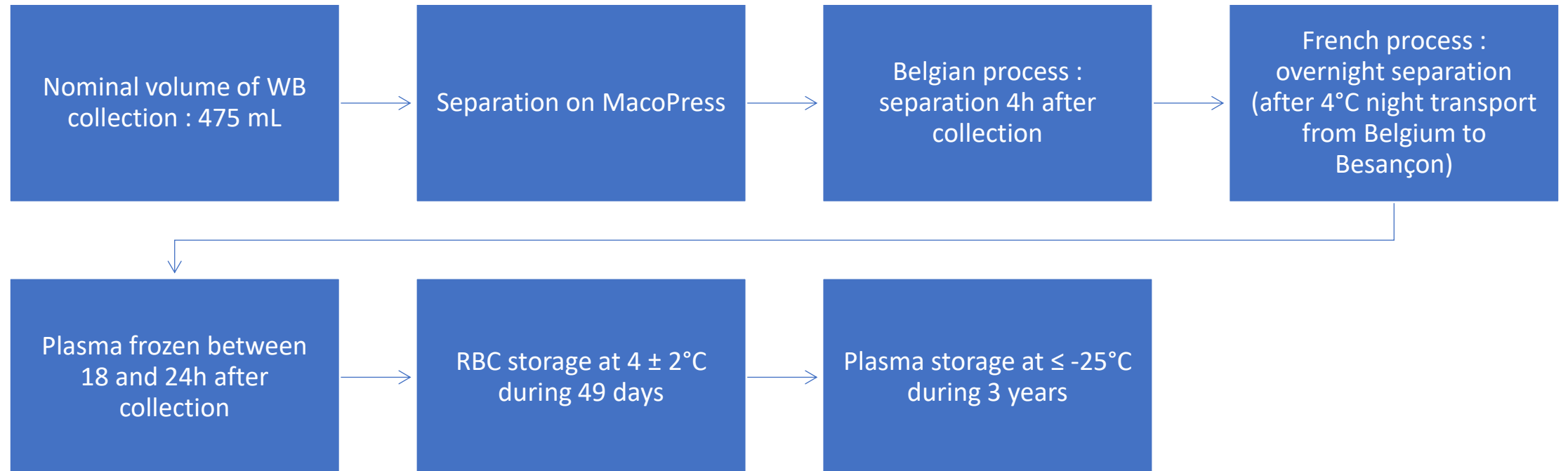
Top&Bottom bags



16 DEHT-SAGM



Production process



Sampling and analyses



RBC

D1

D21

D28

D35

D42

D49

Day 1

- ✓ Hb
- ✓ Hct
- ✓ rWBC
- ✓ rRBC*
- ✓ Platelets*

Storage

- ✓ Hb
- ✓ Hct
- ✓ pH
- ✓ pO₂*
- ✓ pCO₂*
- ✓ Glucose
- ✓ Lactate
- ✓ K⁺
- ✓ ATP
- ✓ Haemolysis

plasma

D1

6M

1Y

2Y

3Y

Day 1

- ✓ rWBC
- ✓ rRBC
- ✓ platelets

Storage

- ✓ FVIII
- ✓ fibrinogen
- ✓ Total proteins
- ✓ TAT*
- ✓ α₂ antiplasmin*
- ✓ C3a*
- ✓ C5a*

EDQM requirements - 21st edition

Parameter RBC	Acceptance criteria
Haemoglobin (g/unit) ^a	≥ 40
Haematocrit (%) ^a	50 – 70
Residual WBC (10 ⁶ /unit) ^a	≤ 1
Haemolysis (%) ^a	< 0.8 % of the total red cell mass

Parameter Plasma	Acceptance criteria
Residual WBC (/μL) ^a	< 100
Residual RBC (/μL) ^a	< 6000
Residual PLT (/μL) ^a	< 50x10 ³
Factor VIII (IU/mL)	Average ≥ 0.70

^aAt least 90% of the units must be compliant

Results at day 1

Donor characteristics

N=32	PAGGSM	SAGM
Volume (mL)	477 ± 6	479 ± 6
Donor Hb (g/dL)	14.3 ± 1.2	14.5 ± 1.1
Donor Ht (%)	45 ± 3	45 ± 3
Donor BMI	24 ± 3	25 ± 5

RBC parameters

N=31	PAGGSM	SAGM
Volume (mL)	265 ± 20	273 ± 15
Hb (g/U)	50.2 ± 6,3	52.0 ± 4.8
Hct (%)	59 ± 3	59 ± 3
WBC 10 ⁶ /U	0.06 ± 0.05	0.04 ± 0.03

Plasma parameters

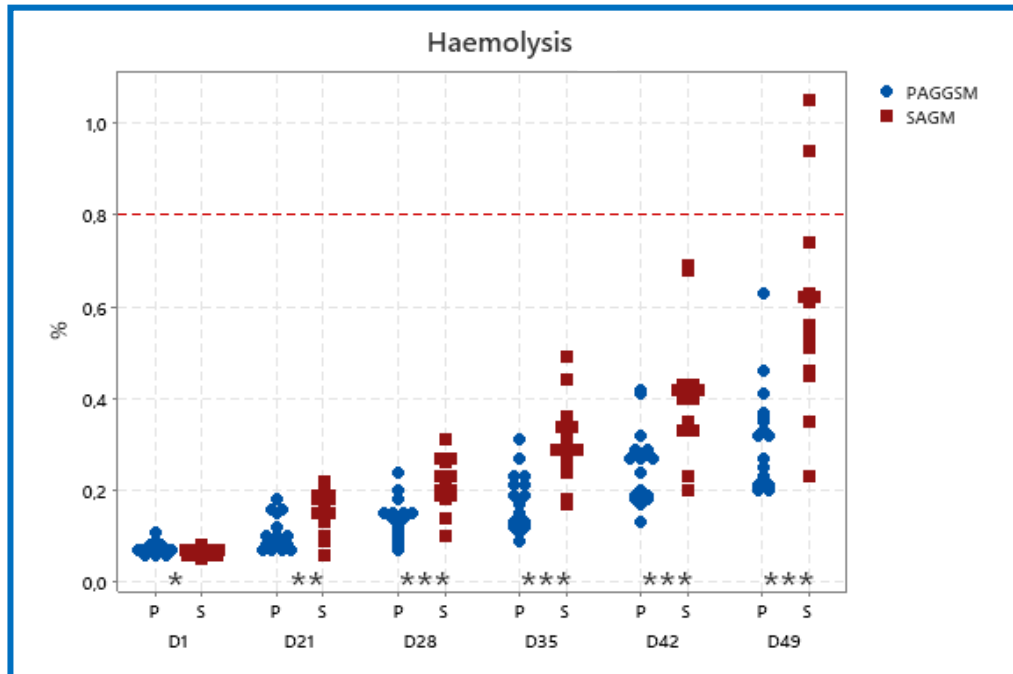
N=32	PAGGSM	SAGM
Volume (mL)	295 ± 18	294 ± 15
Residual WBC (10 ⁶ /L)	9 ± 10	9 ± 8
Residual RBC (10 ⁹ /L)	0.3 ± 0.3	0.3 ± 0.3
Residual PLT (10 ⁹ /L)	6.2 ± 3.5	5.6 ± 2.1
Proteins (g/L)	61 ± 3	61 ± 3
Factor VIII (UI/mL)	0.94 ± 0.24	0.94 ± 0.19
Fibrinogen (g/L)	2.75 ± 0.51	2.91 ± 0.59

All RBC and plasma were compliant to EDQM requirements

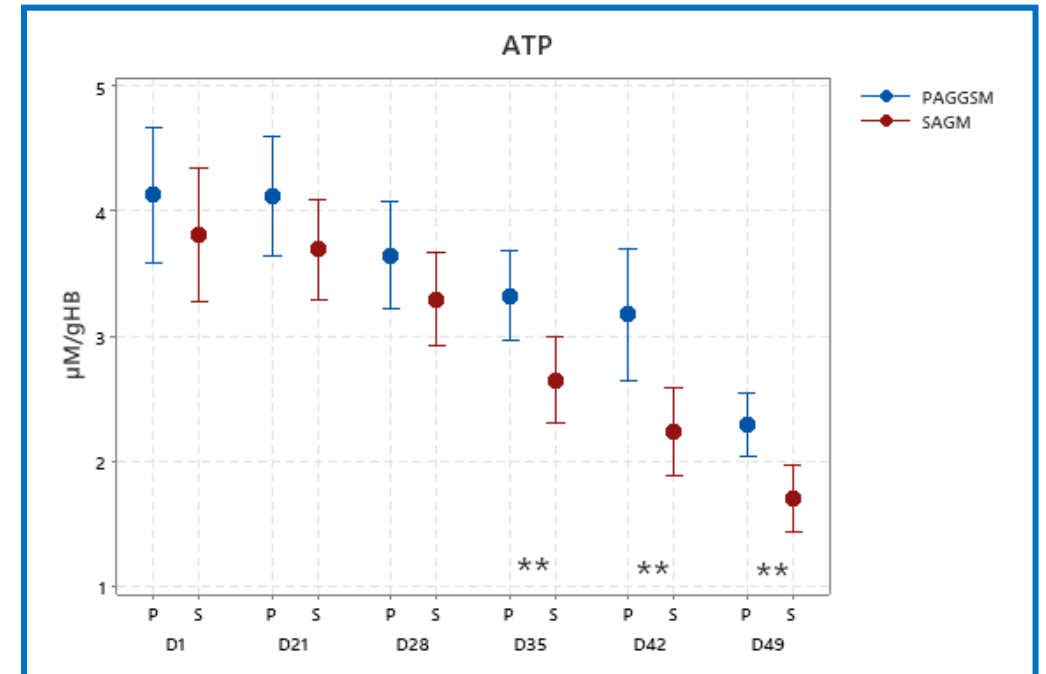
Results for RBCC

Significance levels are presented as * p<0.05, **p<0.01,***p<0.001

At day 49, 100% PAGGSM RBC were compliant with EDQM requirements, versus 87% SAGM RBCC



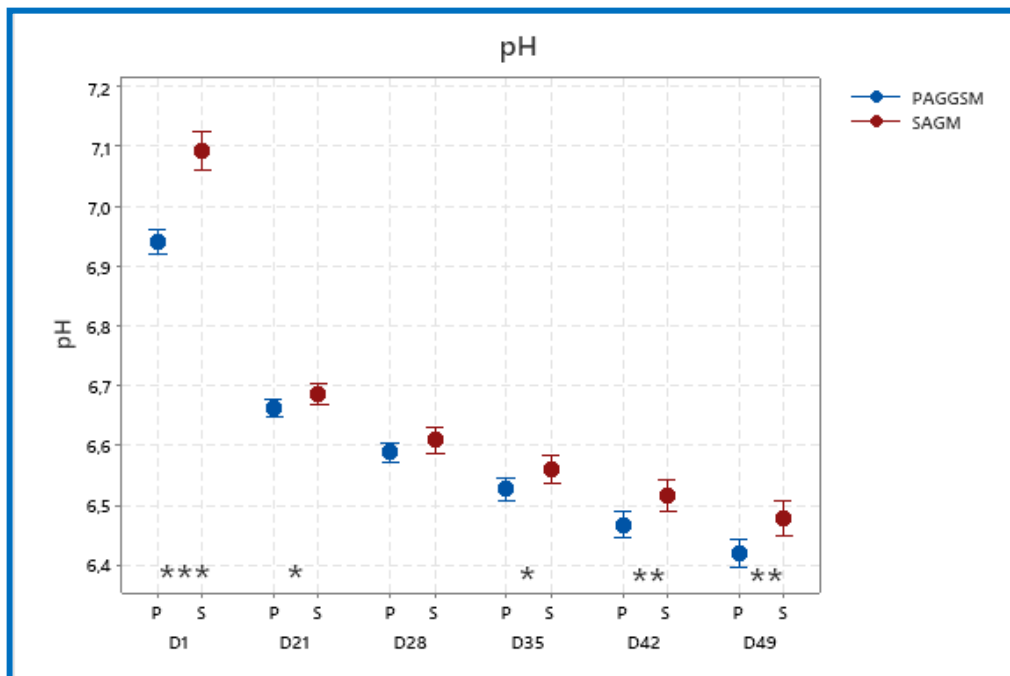
	PAGGSM (n=16)	SAGM (n=16)
D1	0.07 ± 0.01	0.06 ± 0.01
D49	0.32 ± 0.11	0.59 ± 0.21



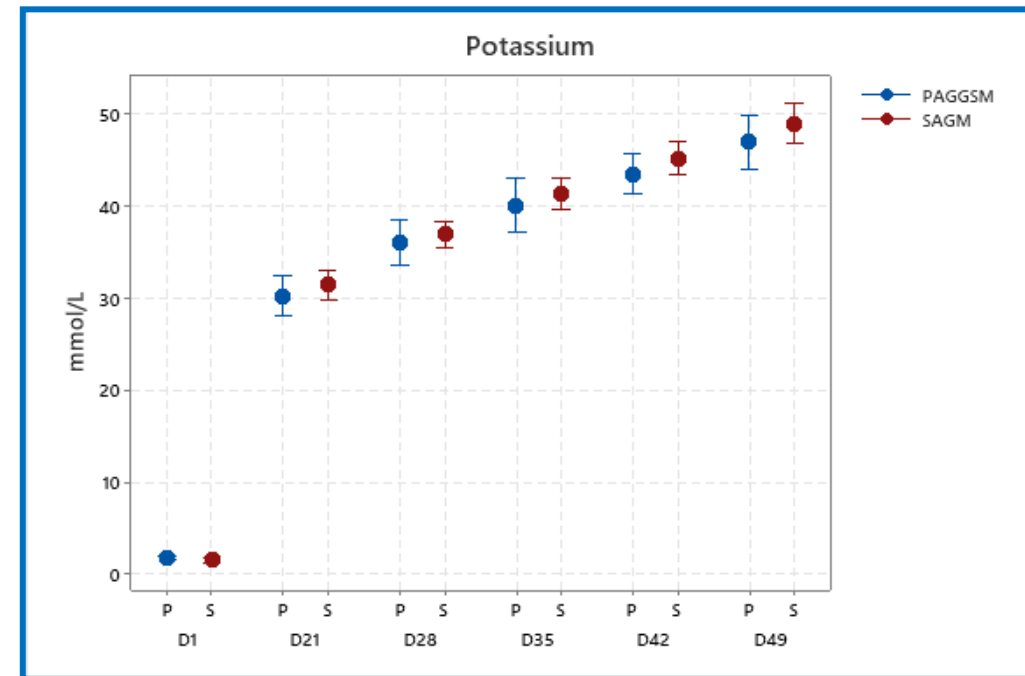
	PAGGSM (n=16)	SAGM (n=16)
D1	4.13 ± 1.02	3.81 ± 0.97
D49	2.29 ± 0.48	1.70 ± 0.49

Results for RBCC

Significance levels are presented as * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$



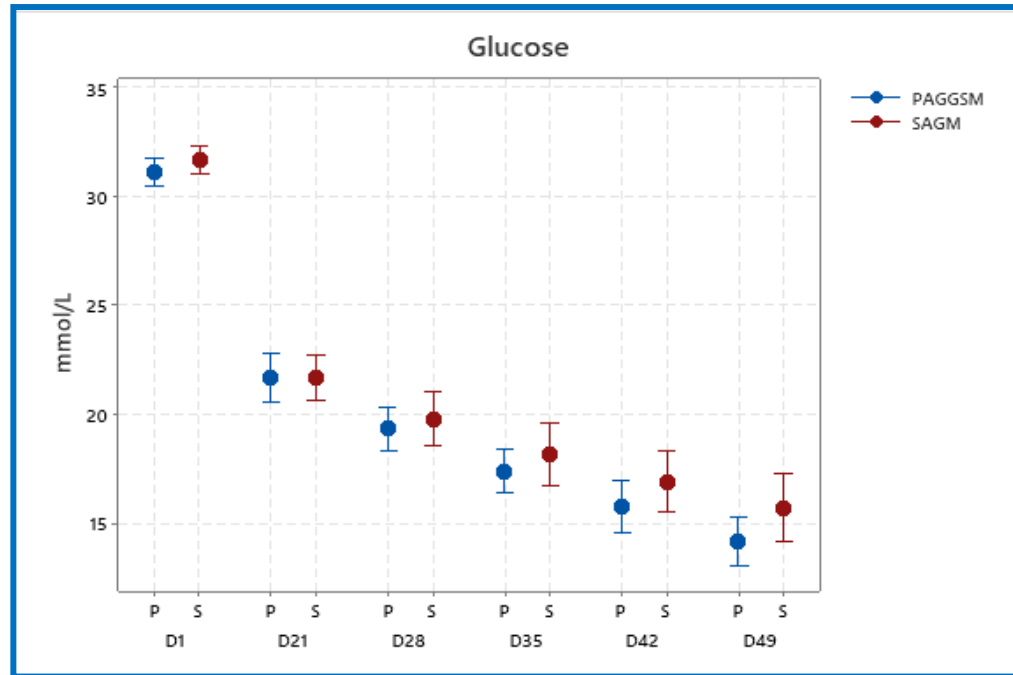
	PAGGSM (n=16)	SAGM (n=16)
D1	6.94 ± 0.04	7.09 ± 0.06
D49	6.42 ± 0.04	6.48 ± 0.05



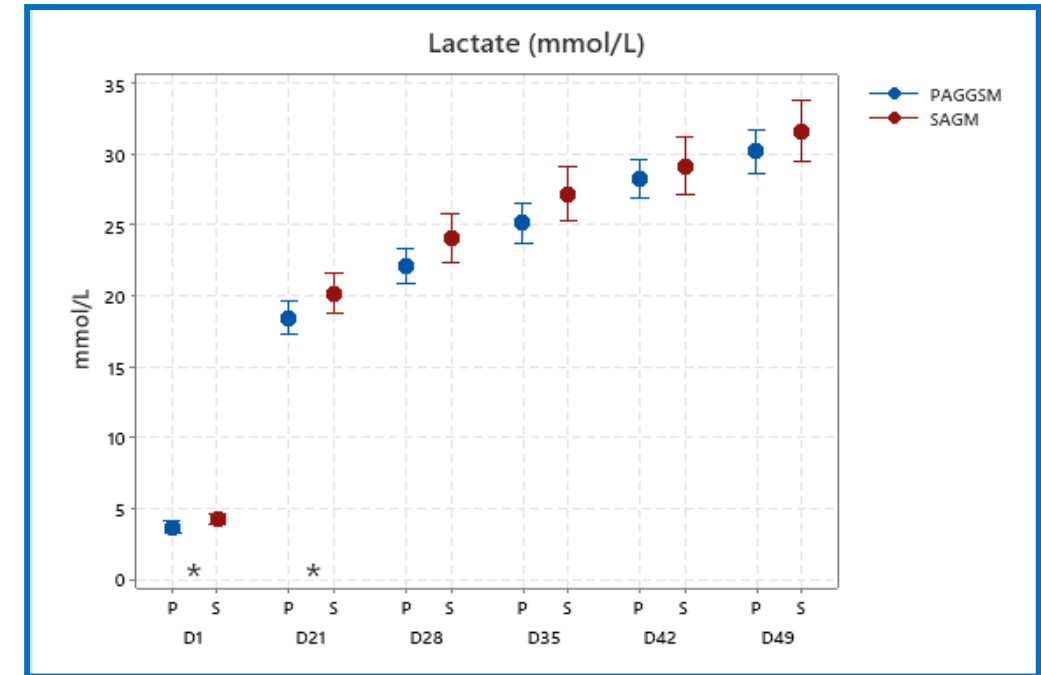
	PAGGSM (n=16)	SAGM (n=16)
D1	1.8 ± 0.5	1.6 ± 0.5
D49	46.9 ± 5.5	48.9 ± 3.8

Results for RBCC

Significance levels are presented as * p<0.05, **p<0.01,***p<0.001

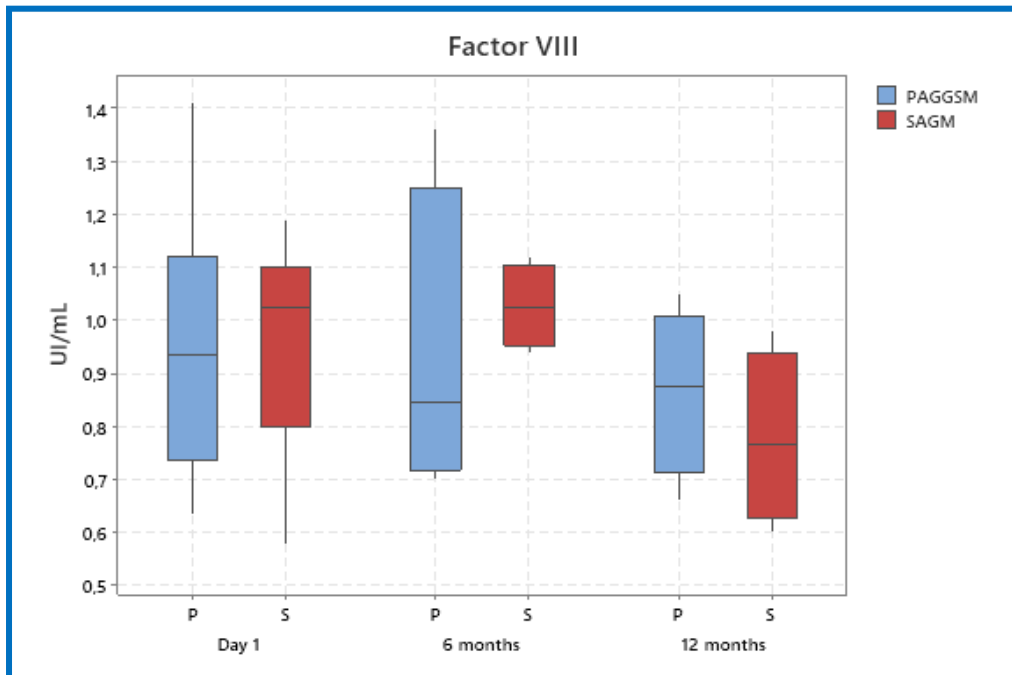


	PAGGSM (n=16)	SAGM (n=16)
D1	31.1 ± 1.1	31.6 ± 1.1
D49	14.2 ± 2.1	15.7 ± 2.8



	PAGGSM (n=16)	SAGM (n=16)
D1	3.7 ± 0.8	4.3 ± 0.6
D49	30.3 ± 2.9	31.7 ± 3.8

Results for plasma



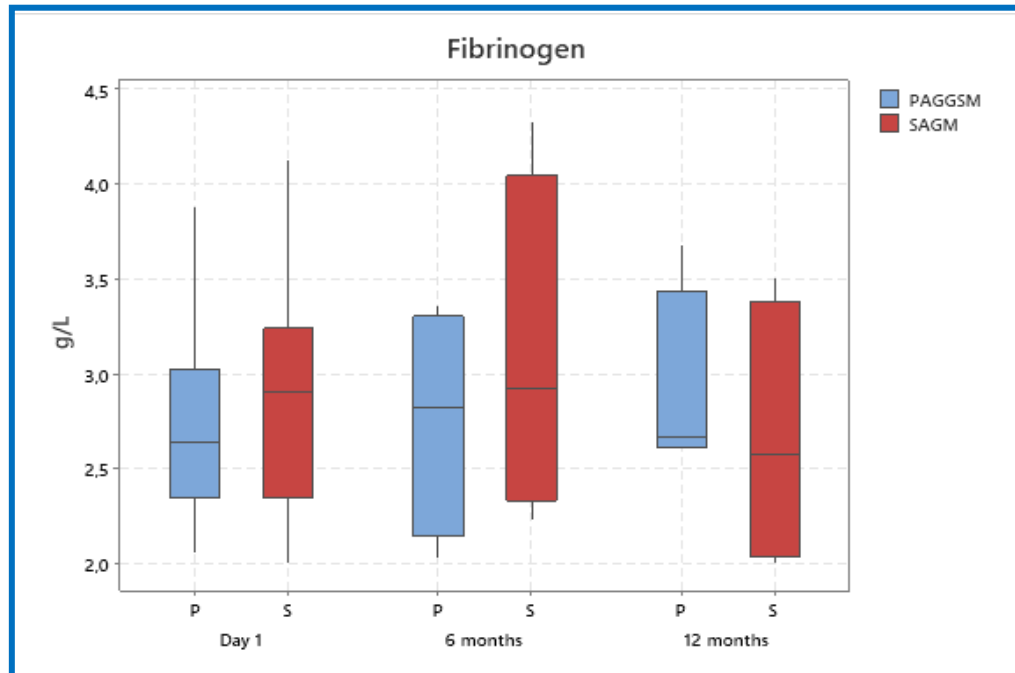
median	PAGGSM	SAGM
D1 (n=16)	0.94	1.03
M6 (n=4)	0.84	1.03
M12 (n=4)	0.88	0.77

Factor VIII recovery % (median value)

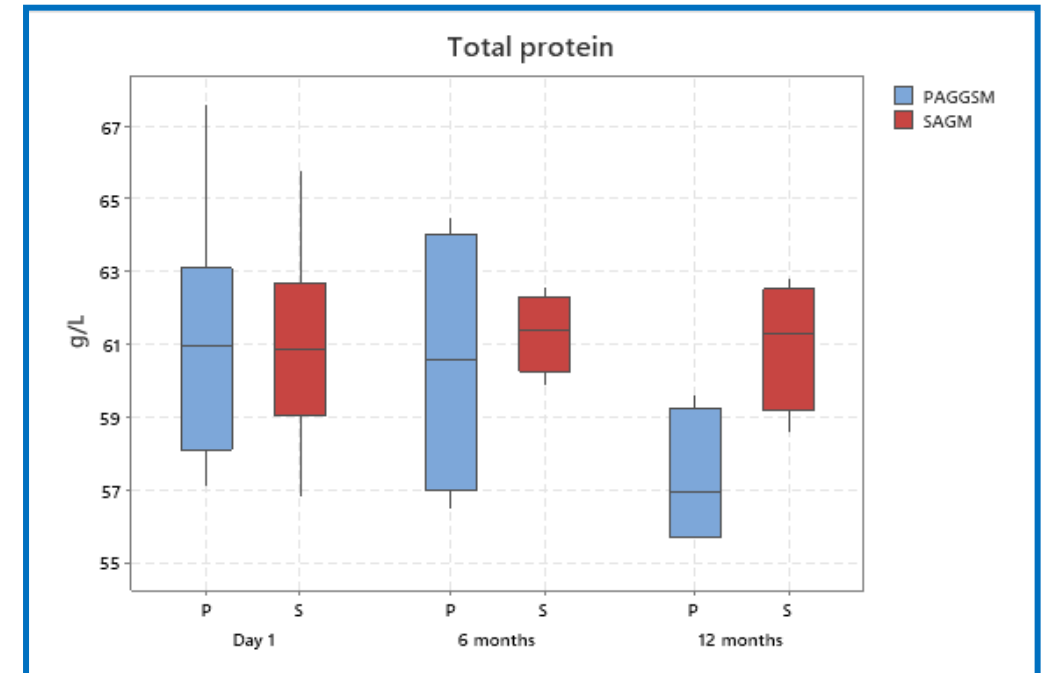
	PAGGSM	SAGM
M6 / D1 (n=4)	95	93
M12 / D1 (n=4)	90	91

All plasma units were compliant to EDQM requirements

Results for plasma



	PAGGSM	SAGM
D1 (n=16)	2.64	2.91
M6 (n=4)	2.82	2.93
M12 (n=4)	2.67	2.58



	PAGGSM	SAGM
D1 (n=16)	60.9	60.9
M6 (n=4)	60.6	61.4
M12 (n=4)	57.0	61.3

Conclusion

All plasma and RBC were compliant to the EDQM parameters at day 1

During the storage of plasma at 6 and 12 months, the parameters Factor VIII, Fibrinogen and Protein were compliant to the EDQM parameters (waiting for results at 2 and 3 years), plasma PAGGSM/SAGM are stored in the same way

The parameters controlled during RBC storage from day 1 to day 49 were similar for pH, glucose, lactate and potassium. For haemolysis and ATP, we obtained an improvement with PAGGSM solution, nevertheless all RBC were compliant until day 42

Very good collaboration EFS / SFS for these Franco-Belgian study

Acknowledgments

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- Thanks to specific EFS laboratory in Nancy and Lyon for haemostasis and ATP analyses

