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PROGRAM OF ABSTRACTS

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POSTER PRESENTATIONS

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Reduction in Compound Adsorption Device Exposure Time for Pathogen Inactivated Platelet Components Treated With Amotosalen and an LED-Based Illumination Device

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BACKGROUND: The INTERCEPT® Blood System for Platelets uses amotosalen and ultraviolet A (UVA) light to inactivate a broad spectrum of pathogens and leukocytes in donor platelet concentrates (PCs). A compound adsorption device (CAD) is a component of the disposable kits of the amotosalen/UVA pathogen reduction technology (PRT). PCs in platelet additive solution (PAS) treated with Large Volume (LV) or Dual Storage (DS) platelet kits are currently exposed to CAD for a minimum of 6 hours to adsorb residual amotosalen from PCs after UVA illumination. The LV platelet kit has a 1.0L CAD container, whereas the DS platelet kit has a 1.3L CAD container.

The replacement of the broad wavelength UVA bulb with a narrower wavelength LED as illumination source may allow for the reduction of the minimum CAD exposure time, while maintaining residual amotosalen concentrations below the established threshold of 7.5 µM.

AIMS: To evaluate a reduced CAD exposure duration for residual amotosalen removal in apheresis PCs in PAS after treatment with amotosalen (LV and DS platelet kits) and UVA illumination using an LED light source.

METHODS: Apheresis PCs at high volume (411 - 427 mL) in PAS collected using the Amicus® Separator System were treated with amotosalen/UVA using LV or DS platelet kits and an LED light source (n=18 per platelet kit type). Amotosalen concentration was measured before and after UVA illumination and at hour-long intervals between two and six hours of CAD exposure.

RESULTS: The mean amotosalen concentration was below the threshold of ≤7.5 µM after 3 hours of exposure to CAD for platelets treated with either the DS or LV platelet kit and an LED light source. All replicates were below the 7.5 µM threshold after exposure to CAD for 4 hours for the DS platelet kit and 5 hours for the LV platelet kit.

SUMMARY/CONCLUSIONS: These results show that the amotosalen/UVA PRT using an LED light source allows for a reduction in the minimum CAD exposure time to 5 hours for PCs treated with the LV platelet kit and 4 hours for PCs treated with the DS platelet kit.

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Table 1: Amotosalen Concentration Before and After Illumination and Following Different CAD Exposure Durations

Sample	LV Processing Set, N=18	DS Processing Set, N=18
Pre-Illumination Amotosalen (µM)	122.52 ± 2.58	121.25 ± 2.24
	(117.37 - 125.55)	(117.59 - 126.35)
Post-Illumination Amotosalen (µM)	41.95 ± 4.80	40.58 ± 5.01
	(31.40 - 48.73)	(31.80 - 48.37)
Post-Illumination Amotosalen % Residual (%)	34.2 ± 3.8	33.5 ± 4.1
	(25.5 - 39.8)	(26.5 - 40.2)
Post-CAD Residual Amotosalen 2 hours (µM)	11.54 ± 3.22	9.07 ± 2.28
	(5.58 - 19.45)	(6.24 - 14.37)
Post-CAD Residual Amotosalen 3 hours (µM)	6.16 ± 2.19	4.43 ± 1.75
	(2.66 - 12.03)	(2.76 - 8.38)
Post-CAD Residual Amotosalen 4 hours (µM)	3.36 ± 1.54	2.24 ± 1.01
	(1.23 - 7.96)	(1.07 - 4.62)
Post-CAD Residual Amotosalen 5 hours (µM)	1.89 ± 0.96	1.15 ± 0.55
	(0.66 - 4.83)	(0.53 - 2.41)
Post-CAD Residual Amotosalen 6 hours (µM)	1.08 ± 0.62	0.66 ± 0.32
	(0.38 - 3.04)	(0.30 - 1.49)

Evaluation of the Impact of Amotosalen/UVA-Based Treatment on Clot Retraction Capacity and Other Key Functional Endpoints for Pathogen Inactivated Platelet Components

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BACKGROUND: The INTERCEPT® Blood System for Platelets uses amotosalen and ultraviolet A (UVA) light to inactivate a broad spectrum of pathogens and leukocytes in donor platelet concentrates (PCs). Key functional parameters for assessing platelet quality include aggregation assays with adenosine diphosphate (ADP) and thrombin to probe platelet activation pathways; PAC-1 binding as an indicator of a platelet's capacity to participate in aggregation; and α-granule secretion, measured by P-selectin surface expression and a critical element of hemostasis and thrombosis. Clot retraction capacity (Muraoka *et al*., Platelets, 2023) has emerged as a more physiologically relevant measure of platelet quality, providing an integrated assessment of platelet function, fibrin mechanics, and clot stability.

AIMS: Evaluate the clot retraction capacity and other key parameters for PCs treated using Amotosalen/UVA compared to untreated PCs.

METHODS: Apheresis PCs in 100% plasma were pooled to create eight experimental replicates (N=8) which were split into two identical units with a platelet dose of 3.0 - 4.5×10^{11} platelets/unit in 278.9 - 338.8 mL. The Control units remained untreated and the Test units were treated with amotosalen/UVA. *In vitro* platelet function parameters, including clot retraction, were evaluated before treatment and after 5 days of storage.

RESULTS: Amotosalen/UVA treatment of PCs induces modest increases in baseline activation, reflected by higher P-selectin positivity at Day 5, but does not compromise key functional parameters (**Table 1**). Clot-retraction analysis revealed a slight increase in maximal OD at Day 5 for amotosalen/UVA treated PCs, while retraction kinetics and overall clot-size reduction remained equivalent for Test and Control. There was no impact on platelet activation capacity as shown by PAC-1 binding. Light-transmission aggregometry demonstrated no significant loss of aggregation capacity in response to ADP or thrombin. pH was well maintained through 5 days of storage.

SUMMARY/CONCLUSIONS: Amotosalen/UVA pathogen inactivation yields only minor alterations in platelets pre-activation without impairing aggregation, secretion, or contractile function after five days of storage.

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Table 1: *In Vitro* Platelet Function of Untreated and Pathogen Inactivated Platelet Components, N=8

Parameter	Day 1 (Input)	Day 5 Control (Untreated)	Day 5 Test (Amotosalen/UVA)
Volume (mL)	303.6 ± 26.7	299.3 ± 25.4	**290.5 ± 27.4**
	(278.9 - 338.8)	(275.5 - 333.4)	**(264.8 - 328.5)**
Dose (x10^{11} platelets)	3.6 ± 0.6	3.4 ± 0.5	**3.1 ± 0.6**
	(3.0 - 4.5)	(3.0 - 4.1)	**(2.5 - 3.9)**
pH (22°C)	7.3 ± 0.1	7.5 ± 0.1	**7.4 ± 0.1**
	(7.2 - 7.4)	(7.4 - 7.6)	**(7.3 - 7.4)**
P-selectin (basal, %)	15 ± 10	22 ± 15	**32 ± 17**
	(2 - 37)	(4 - 45)	**(9 - 53)**
P-selectin (activated with TRAP-6, %)	87 ± 12	68 ± 16	71 ± 21
	(67 - 98)	(43 - 96)	(34 - 96)
PAC-1 (basal, %)	1 ± 1	1 ± 1	2 ± 1
	(0 - 3)	(1 - 2)	(1 - 3)
PAC-1 (activated with TRAP- 6, %)	68 ± 28	53 ± 17	54 ± 24
	(6 - 9)	(33 - 86)	(10 - 83)
Percentage of maximal aggregation with ADP (%)	38 ± 21	30 ± 16	33 ± 14
	(17 - 69)	(8 - 57)	(12 - 51)
Percentage of maximal aggregation with Thrombin (%)	95 ± 4	93 ± 14	85 ± 19*
	(90 - 105)	(74 - 107)	(54 - 116) *n=7
Maximal OD (peak clot formation)	2.1 ± 0.1	2.1 ± 0.1	**2.2 ± 0.1**
	(1.9 - 2.3)	(2.0 - 2.4)	**(2.1 - 2.4)**
Retraction Coefficient (retraction rate)	0.6 ± 0.1	0.6 ± 0.1	0.6 ± 0.2
	(0.5 - 0.7)	(0.5 - 0.7)	(0.2 - 0.7)

Note: Test data in bold is statistically significantly different from Control (p≤0.05)

INTERCEPT Treatment on Double Dose Pooled Platelets (PC-DS) With Low Volume (350-375ml) and High Platelet Content (7-8.10^{11})

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BACKGROUND: According to INTERCEPT validation standards, pathogen inactivated double-dose pooled platelet concentrates (PC-DS) should have a volume between 375 and 420 mL and a platelet content between 7.0 and 8.0 ×10^{11} prior to treatment. This arbitrary volume criterion was intended to ensure adequate platelet storage up to day 7 rather than optimal pathogen inactivation efficacy, which is validated for volumes between 300 and 420 mL. The lower volume limit of 375 mL was only defined to optimize platelet concentrate preparation and to avoid high platelet content in a low plasma/additive solution volume. However, according to the manufacturer's instructions for use, the maximum authorized platelet concentration is 2300 G/L, which corresponds to a minimum volume of 348 mL for a platelet content of 8.0 ×10^{11}. Moreover, there are no theoretical restrictions to pathogen inactivation of PC-DS with volumes between 350 and 375 mL and a platelet content between 7.0 and 8.0 ×10^{11} that represents approximately 18% of PC-DS production at Grand Est French Blood Establishment.

AIMS: This study aimed to demonstrate that INTERCEPT-PC-DS maintain adequate quality under low-volume (350–375 mL) and high platelet content (7.0–8.0 ×10^{11}) conditions.

METHODS: PC-DS were produced in PAS-E (TPAS+) with volumes ranging from 350 to 375 mL and a platelet content between 7.0 and 8.0 ×10^{11}. There were sampled after pathogen inactivation treatment at day 2 (final product), as well as after storage up to day 7, to assess swirling index, platelet count, pH, blood gas parameters and glucose consumption.

RESULTS: All PC-DS produced respected a platelet content < 2300 G/L (1960 +/- 71 G/L, min: 1880 G/L, max: 2095 G/L). Evolution of pH and blood gas parameters were comparable to those observed in PC produced under similar conditions (PC-DS stored in T-PAS+, with reference values derived from another study) and within standard volume and concentration ranges (**see Table**). Despite the high platelet concentration, swirling was clearly visible at day 7 for all platelet concentrates (100% +++) and glucose consumption appeared comparable compared with reference values (1.4 vs 1.1 mM) (**see Table**). Thus, PC-DS evaluated in this study, although characterized by a higher platelet concentration, exhibited lower glucose consumption than standard PC-DS stored in PAS-C (Intersol), which are known to consume all available glucose before the end of storage period.

CONCLUSION: Rather than adding storage solution in order to reach a volume > 375 mL, we demonstrated that PC quality during storage was not compromised by high platelet concentration and low volume. In line with the manufacturer's instructions allowing INTERCEPT treatment of PC-DS with concentrations < 2300 G/L, this study provides strong additional evidence supporting the good quality of concentrated platelet products. Accordingly, EFS Grand Est authorizes PC meeting these criteria without performing an additional manipulation requiring a sterile connection.

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	Platelet content (G/L)	Swirling	pH	pO_2 (mmHg)	pCO_2 (mmHg)	Glucose (mM)
Final product D2 N= 10	1918 ± 69	100% +++	7.037 ± 0.032	94.1± 19.6	42.1± 1.8	6.4 ± 0.8
D7 N= 6	1842± 68	100 % +++	7.152 ± 0.099	111.5 ± 5.4	21.7 ± 1.0	1.4 ± 1.2
Reference values at D7 (control PC-DS in PAS-E from another study) N= 17	1472 ± 234	60% +++ 40 % ++	7.060 ± 0.080	120.8 ± 14.0	19.4 ± 1.6	1.1 ± 0.8

Introduction of Pathogen-Reduced Double-Dose Apheresis Platelets in a Tertiary Teaching Hospital in Thailand – Impact on Component Characteristics and Clinical Use

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BACKGROUND: Pathogen Inactivation (PI) was reported in the literature to increase blood safety and reduce adverse reactions. Due to economical and logistical reasons, we implemented double dose (DD) treatment of apheresis platelet concentrates (APCs) in combination with shelf-life increase from 5 to 7 days. In a pilot study, we treated ~10% of our DD APCs over a period of 6 months with PI to assess the impact on product characteristics and clinical use.

AIMS: Assessment of the impact of PI-treatment of DD APC on product characteristics and clinical use.

METHODS: DD APCs in 35% plasma and 65% PAS-C (InterSol, Fresenius-Kabi, Germany) were collected (randomly assigned) with an MCS+ device (Haemonetics, U.S.A.), an Amicus device (Fresenius-Kabi), or a Trima Accel device (Terumo BCT, U.S.A.). Pathogen inactivation treatment was conducted within 24 h post collection with the amotosalen/UVA (AS) method (INTERCEPT Blood System Dual Storage (DS) Processing Set for Platelets, Cerus Corporation, U.S.A.). Platelet count was assessed with a MYTHIC 22 Blood Analyzer (Cormay Diagnostics, Poland), the desired platelet dose per platelet component (PC) was ≥2.4 x 10^{11}. Statistical analysis was conducted with the two sample- t-test.

RESULTS: Eighty-six PCs were included in the conventional (C) arm (02-03, 2025), 83 were included in the PI arm (03-09, 2025). In the C-arm, 65% of PCs were collected with an MCS+, 28% with an Amicus and 7% with a Trima device. In the PI-arm, 82% of PCs were collected with an MCS+ and 18% with an Amicus device. The average platelet dose in the conventional arm per PC was 3.7 ± 0.6 x 10^{11}, in the PI-arm 3.1 ± 0.5 x 10^{11} ($p<0.05$). In both arms, the platelet yield of MCS+ collections was 8-10% lower compared to Amicus and Trima ($P<0.05$). In both arms there was no significant difference in platelet dose related to ABO blood group ($p>0.05$). In the C-arm, on average transfusions were conducted on day (D) 3.0 ± 1.6, in the PI-arm on D 5.1 ± 2.1 ($p<0.05$). The majority of PCs in the C-arm were transfused in the ward for internal medicine (51.2%) followed by surgery (29.1%) and the emergency room (ER) (12.8%). In the PI-arm, the majority of PCs were transfused in the internal ward (62.7%), followed by surgery (21.7%) and the ER as well as the pediatrics department (both 6% respectively). No increased unexpected adverse events rate were reported in the PI-arm.

SUMMARY/CONCLUSIONS: The transfusion practice (use by specialty) was not different between the arms, no safety outcome differences were reported. PI-PCs have a lower platelet dose, as result of an average processing loss of 10-15% as known from the literature, the different distribution of apheresis devices in the study arms might have contributed to that as well. The PI PCs were transfused significantly later compared to C-PCs, likely due to prolonged shelf-life allowing reduction of wastage. The increased shelf-life has potential to increase product availability, reduction of wastange and supply continuity in remote centers.

Amotosalen/UVA Inactivation of TTI-Associated Bacteria in Platelet Components

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BACKGROUND: The INTERCEPT® Blood System for Platelets uses a combination of amotosalen and UVA light to inactivate pathogens and leukocytes in platelet concentrates (PC) to reduce the risk of transfusion-transmitted infections (TTIs). The continued risk and occurrence of TTIs highlights the importance of evaluating pathogen reduction against clinically relevant bacteria.

AIMS: To evaluate the inactivation through Day 7 post-treatment of 6 bacteria from previous TTI cases in non-pathogen reduced buffy coat platelet concentrates (BCPC) and a bacterial strain from a more recent case of a *Staphylococcus ureilyticus* contaminated pathogen reduced apheresis PC.

METHODS: BCPC units were pooled (420 mL; platelet dose 7.1–8.0 $\times 10^{11}$), spiked with TTI-associated bacteria (**see Table 1**), and treated with amotosalen/UVA. Samples were collected pre- and post-illumination, post-CAD, and on Days 3, 5, and 7 for bacterial enumeration.

Growth kinetics of *S. ureilyticus* were assessed by inoculating 10–25 CFU into apheresis PC and measuring titer over 7 days. Inactivation capacity was evaluated by spiking ~319 mL of apheresis PC with *S. ureilyticus*, treating with amotosalen/UVA, and sampling on Days 5 and 7.

RESULTS: Amotosalen/UVA treatment resulted in inactivation of TTI-associated bacteria in BCPC and apheresis PC, with no viable bacteria detected up to Day 7 for all strains tested (**Table 1**). For growth assessment in apheresis PC, *S. ureilyticus* grew to 1.3 ± 0.3, 5.1 ± 0.9, 8.4 ± 0.2, and 8.6 ± 0.0 log CFU/mL in PC on days 1, 2, 4, and 7, respectively.

SUMMARY/CONCLUSIONS: Amotosalen/UVA effectively inactivates to sterility TTI-associated bacteria in BCPC and in apheresis PC through the end of platelet shelf-life. Investigation of *S. ureilyticus* supports post-PR contamination as the titer of bacteria at the treatment-relevant timepoint for this case (Day 2) was below the inactivation capacity of the INTERCEPT Blood System for platelets. This data highlights the robustness of pathogen reduction against multiple TTI associated bacteria.

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Table 1: Amotosalen/UVA Treatment of TTI-Related Bacteria up to Day 7 Post-Treatment

Platelet Component	Bacteria	Log Reduction (Log cfu/mL)
Buffy Coat Platelet Concentrates (BCPC)[a]	*Cutibacterium acnes*	6.9 ± 0.1
	Klebsiella pneumoniae	2.9 ± 0.1
	Pseudomonas aeruginosa	5.4 ± 0.2
	Serratia marcescens	4.6 ± 0.2
	Staphylococcus aureus	7.7 ± 0.2
	Staphylococcus epidermidis	6.8 ± 0.0
Apheresis Platelet Concentrates (PC)[b]	*Staphylococcus ureilyticus*[a]	6.7 ± 0.2

a. The strains used in BCPC were from TTI-cases involving non-pathogen reduced platelets.

b. *S. ureilyticus* strain isolated in a TTI-case involving a pathogen reduced apheresis platelet product in France in 2024.

Pilot Production Study of Pathogen Reduced Double Dose Platelet Components from Eight Buffy Coats Pooling in Platelet Additive Solution

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BACKGROUND: Platelet transfusion safety remains challenged by bacterial contamination and residual leukocytes that persist with conventional preparation methods. Pathogen inactivation (PI) technologies provide additional safety by inactivating infectious agents, largely preserving platelet function. This study investigates the production feasibility and product quality of PI-treated double-dose (DD) platelet components prepared from eight pooled buffy coats (BCs) in platelet additive solution (PAS).

AIMS: To evaluate the product quality and recovery of pathogen reduced whole-blood derived DD platelet components in PAS.

METHODS: Whole blood donations (450 mL, top-bottom bags with inline red cell filter, Fresenius Kabi, Germany) were collected from voluntary donors, stored overnight, centrifuged (3340g, Sorvall BP8, Thermo Scientific, Germany) and processed (CompoMat G5, Fresenius Kabi) to obtain BCs (Volume 40mL). After 2 hours resting, eight ABO-identical BCs were pooled under addition of PAS-C (Intersol, Fresenius Kabi) and washed 3 times with 280mL PAS-C using an Octopus Pooling Kit (FT526AA, CompoStop, Fresenius Kabi). Platelets were centrifugated (390g, Sorvall BP8, Thermo Scientific), leucofiltrated by the pooling kit, separated by a Separation Stand (Teruflex, Terumo BCT, U.S.A.) and treated with Amotosalen/UVA (INTERCEPT Blood System Dual Storage Processing Set, Cerus Corporation, USA). Platelet count (Hematology Analyzer, Beckman Coulter, U.S.A), volume and pH (pH meter, Sartorius, Germany) were assessed at baseline (Day 1) and during storage (Day 2, 5 and 7).

RESULTS: Twelve PI-treated DD pooled platelet components in 59% PAS and 41% plasma were produced. The DD platelet units had an average platelet count of 6.0 ± 0.7 x 10^{11} per unit, a mean volume of 406.1 ± 6.7 mL and plasma to PAS ratio of 41.0 ± 0.6%, fulfilling PI-treatment requirements. Following PI-treatment and aliquoting, the average platelet count was 2.8 ± 0.3 x 10^{11} on Day 2, 2.7 ± 0.3 x 10^{11} on Day 5 and 2.6 ± 0.3 x 10^{11} on Day 7 per unit. The average platelet recovery rate was 91.8%, slightly higher compared to 88.9% in single dose PI-treated, routine produced apheresis platelets. Platelet loss during storage was low at Day 5 and Day 7 (recovery rate 88.8% and 86.9% respectively), indicating efficient preservation of platelet yield after PI-treatment. pH values remained stable at 7.1 ± 0.1 on Day 5 and 6.9 ± 0.1 on Day 7.

SUMMARY/CONCLUSIONS: This study demonstrates the successful preparation of whole-blood derived, pathogen-reduced DD platelet components derived from pooling eight BCs with photochemical PI-technology. The resulting adult transfusion dose units maintained consistent platelet count, volume, and pH stability throughout the 7-days storage, supporting their suitability for transfusion. Additionally, the ability to generate two PI treated components from one DD processing set enhances production efficiency and has economic benefits.

Quality Comparison of Platelet Concentrates Produced by Automated and Manual Technology

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BACKGROUND: At the French Blood Establishment (EFS), the process preparation of buffy coats platelets concentrates (BC-PC) can routinely be done automated (separation and expression of buffy coat pool during centrifugation) or manually (separation of buffy coat pool by centrifugation, transfer, semi-automated expression).

AIMS: We aimed to compare the characteristics of the two types of PC created using the different techniques of separation.

METHODS: Two PCs with the same content were obtained by pooling 16 BC and dividing them in two equivalent volumes. The same conservation solution, T-PAS (Terumo), was added to both pools. One BC-PC was then separated automatically, using automated TACSI method (Terumo). The second BC-PC was first centrifuged at 2000g during 8min (Heraeus Cryofuge 16) and separated using Macopress device (Macopharma). After separation, all PCs were treated for pathogen inactivation by addition of amotosalen and exposition to UVA following by an adsorption period (CAD) to reduce amotosalen in a bag during 16 hours overnight. Finally, each PC was divided in two final storage bags. Biological parameters were assessed to compare the two techniques: swirling, visual changes (No abnormal color or visible clots), blood gases, pH, glucose, platelet count and mean platelet volume (MPV). Each analysis was made after the CAD period (Day2), Day5 and Day7 at the end of the conservation period. Statistical analyses were made between each group at the same time of analyze (D2, D5 and D7) ($p<0.05$*).

RESULTS: Swirling was observed in both bags at each time and no differences or visual changes were noticed. MPV values remained stable, in each group automated or manual method, until the end of the PC conservation time at D7. Platelet concentration decreased during time until D7, in each group, with no difference to be noticed between automated or manual method. The pH values increased at D5, with slightly significant higher values with the manual method. At D7, the values decreased almost up to the values at D2, with no differences between the groups. Neither method differed from one to the other regarding the blood gases, pO_2 and pCO_2. pO_2 was quite stable during time in both methods, in comparison with pCO_2 that dropped from half at D5 and stabilized until D7. Finally, glucose concentration decreased in both PCs with automated method and manual method. There still remained glucose at the end of the conservation, at D7 with 0.9 mmol/L in the automated method and 1.4 mmol/L in the manual method. No significant differences were observed between the groups.

CONCLUSION: The comparison between the two types of PCs, produced with an automated method or manual method of separation, did not show significant differences for any of the parameters. This comforts the possible use of both methods in routine.

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	Automated method			Manual method		
	D2	D5	D7	D2	D5	D7
MPV (fL)	9.9±2.2	10.1±2.3	10.3±2.4	9.7±2.0	9.9±2.2	9.9±2.1
Platelet concentration (.10^{11} plt)	3.2±0.4	2.8±0.5	2.6±0.5	3.1±0.3	2.7±0.5	2.5±0.5
pH	6.96±0.14	7.11±0.06	7.02±0.07	7.03±0.03	7.24±0.20*	7.10±0.05
pO_2 (mmHg)	121.1±22.3	116.0±7.9	127.7±14.9	116.8±19.9	110.7±10.5	113.8±9.7
pCO_2 (mmHg)	40.0±3.6	19.5±1.9	18.9±1.9	42.3±1.9	20.2±1.5	19.8±1.2
Glucose (mmol/L)	5.9±0.8	3.2±0.9	0.9±0.7	6.4±0.7	3.6±0.6	1.4±0.8

Comparison of the *In Vitro* Quality of Pathogen-Reduced Apheresis Platelets in 100% Plasma Compared to Pathogen Reduced Apheresis Platelets in 65% Platelet Additive Solution and 35% Plasma

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BACKGROUND: The replacement of 50-70% of donor plasma in platelet concentrates (PCs) by platelet additive solution (PAS) significantly reduces adverse transfusion reactions improving patient outcomes and well-being according to formerly published data. The reduction of plasma proteins including antibodies and chemokines/cytokines is likely contributing significantly to improved patient outcome.

AIMS: After implementation of pathogen inactivation (PI) technology for PCs, adding an additional layer of transfusion safety, we evaluated quality of PI-PCs in PAS compared to *in vitro* quality of PI-PCs in 100% plasma in preparation for PAS implementation.

METHODS: Single-dose apheresis PCs (APCs) in 100% plasma or in 65% PAS-C (InterSol, Fresenius-Kabi, Germany) and 35% plasma were collected from voluntary donors with an MCS+ device (Haemonetics, U.S.A.). PI-treatment was conducted with the amotosalen/UVA method (INTERCEPT Blood System, Cerus Corporation, U.S.A). PCs were incubated until end of shelf at 22°C to 24°C under continuous agitation. WBC count was assessed with an ADAM MC cell counter (NanoEntek, South Korea). Platelet and RBC counts were assessed with an XN 1000 complete blood counter (Sysmex, Japan). pH was assessed with MQuant test strips (Merck, Germany). The swirling score was assessed on a scale of 0-3 (full=3, partial=2, minimal=1, not visible=0) by visual inspection. Bacterial contamination testing was conducted with an BacT/Alert 3D automated blood culture system (Biomereux, France). Statistical analysis was conducted with the two-sample t-test.

RESULTS: Six APCs were collected in 100% plasma (plasma arm, blood group A x1, B x 2, O x 3) with an average volume of 267 ± 30 mL (PI-treatment related volume loss 8.2 ± 0.3%) and an average platelet dose of 3.6 ± 0.6 x 10^{11} per unit (PI treatment related platelet loss 9.8 ± 0.7%) post PI-treatment. Six APCs were collected in 65% PAS and 35% plasma (PAS arm, blood group A x2, B x 1, O x 3) with an average volume of 298 ± 35 mL (PI-treatment related volume loss 5.8 ± 0.6%) and an average platelet dose of 4.2 ± 0.8 x 10^{11} per unit (PI-treatment related platelet loss 7.4 ± 3.2%) post PI treatment. The PI-treatment related volume loss was significantly higher in the PAS arm ($p<0.01$), there was no significant difference in platelet dose loss between the study arms ($p>0.05$). The average pH in the plasma arm was 7.1 ± 0.2 post-PI and 6.8 ± 0.1 at end of shelf-life (day 7). The average pH in the PAS arm was 7.1 ± 0.2 post-PI and 6.8 ± 0.1 at end of shelf-life (day 7). The average swirling score was 3.0 ± 0.0 in both study arms post PI and end of shelf-life (day 7). There were no significant differences in pH and swirling score between the study arms ($p>0.05$). All units in both study arms were negative by bacterial testing at end of shelf life.

SUMMARY/CONCLUSIONS: There were no significant differences in PC quality parameters between both study arms until end of shelf-life (day 7). The only difference was significantly higher PI-treatment-related volume loss, but not platelet dose loss, in the PAS arm. In summary PI-treated APCs in 100% plasma or 65% PAS-C and 35% plasma had acceptable and comparable *in vitro* quality until day 7 of storage.

In Vitro Quality of Pathogen-Reduced Apheresis Platelets in PAS Validated in a Large Tertiary Care Hospital in Thailand

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BACKGROUND: Despite multiple improvements in blood safety in the last decades, the highest incidence of unwanted adverse transfusion reactions (ATRs) is still related to platelet concentrate (PC) transfusion according to published hemovigilance data. It has been reported that the replacement of 50%-70% of plasma by platelet additive solution (PAS) significantly contributes to reduction of ATRs by reduction of immunogenic plasma proteins. Pathogen inactivation (PI) treatment of platelets additionally contributes to a reduction of the ATR rate by inactivation of pathogens and white blood cells according to literature.

AIMS: Aim of our study was the validation of apheresis platelet quality post introduction of PI-treatment and replacement of plasma by PAS to increase PC transfusion safety.

METHODS: Double-dose apheresis PCs (APCs) in 33% plasma and 67% PAS-C (InterSol, Fresenius-Kabi, Germany) were collected with an MCS+ device (Haemonetics, U.S.A.) from voluntary donors and subsequently split into two PCs. One PC was treated within 24 h post collection with amotosalen/UVA (AS) PI (INTERCEPT Blood System, Cerus Corporation, U.S.A.) and kept for 7 days at 22°C-24°C under continuous agitation, the other PC was released for transfusion. Platelet and RBC counts were determined with a Complete Blood Counter, CBC (Dymind, China), and WBC counts were determined with an ADAM MC cell counter (NanoEntek, South Korea). pH was determined with test strips (Kombucha, Thailand). The swirling score was assessed on a scale of 0-3 (full=3, partial=2, minimal=1, not visible=0) by optical inspection. Bacterial sterility was assessed with a BacT/Alert 3D automated blood culture system (Biomerieux, France). Statistical analyses were conducted with the two-sample t-test.

RESULTS: Twenty APCs were included in the study. Residual RBC count was on average $0.01 \times 10^6 \pm 0.01$ per unit, residual WBC count $0.01 \times 10^6 \pm 0.01$ per µl (both pre-PI-treatment). The average volume post-treatment was 337.1 ±16.3 mL, the PI-treatment related volume loss 3.1 ± 1.5%. The average post-treatment platelet count was $4.8 \times 10^{11} \pm 1.0$ per unit, the PI -treatment related platelet loss was 5.2 ± 2.8 % per unit. The average pH was 6.9 ± 0.2 post PI treatment, 6.8 ± 0.1 day 5 ($p>0.05$) and 6.8 ± 0.2 day 7 ($p>0.05$) of shelf life. The average swirling score was 3.0 ± 0.0 post PI-treatment, 2.7 ± 0.5 day 5 ($p<0.05$) and 2.2 ± 0.4 day 7 ($p<0.01$) of shelf-life. All units were negative in bacterial sterility testing performed on day 7.

SUMMARY/CONCLUSIONS: Pathogen-reduced APCs in 67% PAS-C have acceptable *in vitro* quality for transfusion until day 7 of shelf-life. The pH was within local and international guidelines (≥6.4) and did not significantly change during storage, the swirling score dropped slightly with increasing platelet age.

Bacterial Contamination of Platelet Concentrates in China

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BACKGROUND: Due to storage conditions at ambient temperature under agitation, platelet concentrates (PC) are at high risk of bacterial contamination with clinically relevant infectious burdens. Currently there are no additional measures besides skin disinfection, initial blood volume diversion and quality control primary culture in place in China to reduce the risk of bacterial contamination and septic transfusion reactions. The objective of this study is assessment of the overall bacterial contamination rate of platelet concentrates manufactured for transfusion in China.

AIMS: The objective of this study was the assessment of the overall bacterial contamination rate of platelet concentrates manufactured for transfusion in China.

METHODS: All available Chinese and English language publications until December 2023 citing PC bacterial contamination in China from the CNKI, Wanfang, CQVIP databases and Google were screened, selected and analyzed.

RESULTS: After excluding studies with insufficient sample size, double-data and without implementation of initial blood volume diversion, the mean bacterial contamination rate of platelet concentrates in 21 studies conducted between 2006 and 2018 (216,434 PCs tested, 195,902 apheresis and 20,532 whole-blood derived) was 0.13±0.015% (0.098%-0.16%, 95 CI), with a median of 0.12% (initial sampling within 24 h post collection). The most abundant bacterial habitats were skin flora (62.5%), intestinal flora (15.1%), oral/nasophryngeal flora (9.4%) and environmental bacteria (9.4%). Most abundant detected species were *S.aureus* (17.2%), *S.epidermidis* (10.3%), *Cutibacterium spec.* (8.6%), *Peptostreptococcus spec.* (6.9%), *S.haemolyticus* (5.2%) and *Micrococcus spec.* (5.2%).

SUMMARY/CONCLUSIONS: Based on available data, the estimated contamination rate is comparable to studies from other countries/regions during times the same interventions were in place (2006-2018). *S.aureus* was the most abundant detected bacterial species, which is ranked high risk in blood transfusion in the literature. Current platelet concentrate quality control activities in China are not sufficient to prevent contaminated platelet transfusions, and further measures should be considered to mitigate the risk of septic transfusion reactions.

Assessment of the Prevalence of Human Herpesviruses in Plasma for Transfusion Obtained From Whole Blood Donors

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BACKGROUND: Blood products are routinely screened for the presence HIV, HBV, HCV and Treponema. Human Herpesviruses, which pose a risk for immunocompromised patients in primary infection and reactivation, are often neglected. It was reported in the literature that human herpesviruses have the potential to cause severe disseminated infections, and reactivation may be triggered by transfusion or secondary infection. Due to persistence of many Herpesviruses species in white blood cells (monocytes, T-cells, B-cells), transmission followed by reactivation through contaminated platelet units poses a risk as well.

AIMS: Assessment of the prevalence and seroprevalence of human Herpesviruses in voluntary blood donors.

METHODS: Whole-blood derived plasma units from voluntary donors (age: 18-65 years) were tested for human Herpesvirus prevalence by qPCR for HSV-1/2, VZV, CMV, EBV and HHV-6 (RealBest DNA, VectorBest, Russia) with a CFX-96 optical thermocycler (BioRad, U.S.A.). Samples were additionally screened for human Herpesvirus seroprevalence against EBV IgG and IgM (EBV IgG EIA Best and EBV IgM EIA Best, VectorBest), HHV-6 IgG and IgM (HHV-6 IgG EIA Best and HHV-6 IgM EIA Best, VectorBest) and HHV-8 IgG (Vecto-HHV-8-IgG, VectorBest) using a Hydroflex washer (Tecan, Switzerland) and an Infinite F50 reader (Tecan).

RESULTS: 200 plasma units from different male donors were analyzed. All units were negative for the presence of HSV-1/2 DNA, VZV DNA,CMV DNA, EBV DNA and HHV-6 DNA. The seroprevalence (IgG) was 99% for EBV (198/200 donors), 49% for HHV-6 (98/200 donors) and 1.5% for HHV-8 (3/200 donors). The HHV-6 seroprevalence was equally distributed between age groups (42.9%-66.7% positivity rate in each group, standard deviation 8.9%). HHV-8 seroprevalence was only detected in the age group 31-40 years old. Compared to literature, the HHV-6 seroprevalence is below the global average in blood donors in Astana (references: >70%).

SUMMARY/CONCLUSIONS: The relatively low seroprevalence of HHV-8 and HHV-6 poses a risk of primary infection in donors and recipients. Negative PCR results indicate the absence of active viremia in these samples, which is critically important for the safety of donor blood. The persistence of HHV-6 and HHV-8 in white blood cells, which contaminate platelet units, poses an additional risk for transmission (all platelet units in Kazakhstan are pathogen-reduced).

Inactivation of Bacteria, Including Common Environmental Strains, Using Amotosalen/UVA treatment

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BACKGROUND: The INTERCEPT® Blood System for Plasma utilizes amotosalen and ultraviolet A (UVA) light to inactivate a wide range of pathogens in plasma and is available in Europe, the US, and other geographies. The amotosalen/ UVA pathogen reduction technology (PRT) inactivates clinically relevant pathogens found in the environment in plasma to reduce the risk of transfusion-transmitted infections (TTIs).

AIMS: The aim of this study was to evaluate the inactivation of selected environmental bacteria in human plasma using amotosalen and UVA treatment with the INT200 Illuminator that uses LED lights to deliver the UVA light.

METHODS: Human plasma donations were collected and pooled to yield individual units of ~650 mL. The high volume of 650 mL represents a challenge for pathogen inactivation due to the longer light path through the illumination container and the decreased amotosalen concentration of approximately 135 µM, compared to 150 µM at nominal volume (585 mL). A minimum of three replicates were performed for each transfusion-relevant bacteria, including *A. baumannii*, *C. minutissimum*, *L. lactis*, *S. epidermidis*, *S. saprophyticus*, *K. pneumoniae*, *S. aureus*, *P. fluorescens*, and *C. perfringens*, with each replicate consisting of one unit spiked with a single bacterial strain. The contaminated plasma units were treated with amotosalen and UVA light. Samples were taken pre-UVA treatment and immediately after post-UVA treatment (5 mL and 50 mL, respectively) and were analyzed for bacterial titer by plating on appropriate media (100 µL–5 mL/plate).

RESULTS: Treatment of the contaminated plasma units with amotosalen and UVA resulted in robust bacterial inactivation (**Table 1**).

SUMMARY/CONCLUSIONS: Amotosalen/UVA treatment with the INT200 illuminator consistently inactivated high titers of *A. baumannii*, *C. minutissimum*, *L. lactis*, *S. epidermidis*, *S. saprophyticus*, *K. pneumoniae*, *S. aureus*, *P. fluorescens*, and *C. perfringens* at the challenging condition of high plasma volume (650 mL). The data demonstrates robust inactivation, including common environmental transfusion-relevant bacterial strains, using treatment with amotosalen /UVA and the INT200 illuminator with LED light sources.

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Table 1: Bacterial Inactivation Using Amotosalen/UVA Treatment for Human Plasma

Bacteria	Input Titer (Log cfu/mL)	Post-UVA Treatment Titer (cfu/mL)	Log Reduction (Log cfu/mL)
Acinetobacter baumannii	7.4 ± 0.0	0.0 ± 0.0	7.4 ± 0.0*
Corynebacterium minutissimum	7.7 ± 0.2	0.0 ± 0.0	7.7 ± 0.2
Lactococcus lactis	6.4 ± 0.1	0.0 ± 0.0	6.4 ± 0.1*
Staphylococcus epidermidis	7.7 ± 0.1	0.0 ± 0.0	7.7 ± 0.1*
Staphylococcus saprophyticus	7.4 ± 0.1	0.0 ± 0.0	7.4 ± 0.1*
Klebsiella pneumoniae	6.4 ± 0.1	1.4 ± 0.1[a]	5.0 ± 0.2
Staphylococcus aureus	7.8 ± 0.2	0.0 ± 0.0	7.8 ± 0.2*
Pseudomonas fluorescens	7.9 ± 0.1	0.0 ± 0.0	7.9 ± 0.1
Clostridium perfringens	6.7 ± 0.1	0.0 ± 0.0	6.7 ± 0.1*

* No residual bacteria were detected post-treatment.

a. Titer is expressed in log cfu/mL, residual bacteria detected on all replicates post-treatment

Integration of Pathogen Reduction Technology into Operational Plasma Production: An Innovative Approach to Plasma Pooling

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BACKGROUND: INTERCEPT Blood System for plasma (IBS, Cerus) is a Health Canada (HC)-approved pathogen reduction technology. It defines volume (385-650 mL) and red cell content (<4 x 10^6 RBC/mL) specifications for input products. When introducing this technology at Canadian Blood Services (CBS), it was important to maximize plasma unit output per IBS processing set by producing 3 pathogen-reduced (PR) plasma units at 200 mL ± 10%. This output volume meets customer requirements and ensures consistency in product volume across available products. To meet input specifications and maximize productivity per set, an input volume range of 570-650 mL was determined to be necessary, the lower bound of which is above the average volume of plasma components produced by CBS. Hence, either pooling of plasma or changes to production/collection processes were needed. In the absence of a HC licensed pooling set with a suitable configuration and volume capacity, the second approach was pursued using large volume single donor apheresis multi-plasma collections on the Trima Accel system (Terumo BCT).

AIMS: To develop a process that utilized the apheresis multi-plasma collection set for input plasma volume standardization, bypassing the need for additional pooling set consumables while ensuring the final PR plasma met all volume, regulatory and quality specifications.

METHODS: Apheresis multi-plasma was collected from 33 group non-O donors into Trima collection sets (Ref: 82700) using a target collection volume of 650 mL. After disconnecting the donor, instead of sealing and separating each plasma bag as per historical operational practice, the collection line was sealed such that it kept all four bags of the set together. Upon weighing, if the collection was found to be >650 mL, plasma was pooled into two bags of the collection set while excess plasma was separated into the third bag. A sample of plasma was used for residual RBC determination by an in-house flow cytometry-based method, and pooled plasma in the desired volume range (570-650 mL) was pathogen reduced using IBS for Plasma. Output plasma units were frozen overnight in a ≤-18°C freezer, then transferred to a ≤-30-35°C freezer for storage. Plasma was thawed after >30 days frozen storage, sampled and aliquots were frozen at -80°C until tested for plasma *in vitro* quality parameters.

RESULTS: Maximum RBC content determined in 33 collections was 0.02 x 10^6 RBC/mL, and average output PR plasma volume was 199 ± 4 mL/unit. PR plasma met the criterion of ≥0.52 IU/mL FVIII in 75% of units for untreated plasma (CSA Z902-25) upon thawing and quality was found acceptable when compared with published data on similar products.

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SUMMARY/CONCLUSIONS: This study demonstrates that INTERCEPT technology can be flexibly integrated into blood banking operations through creative procedural adaptations. Using the collection set to pool plasma provides a cost-effective solution and removes dependency on additional consumables. The PR product meets Canadian regulatory requirements and is of acceptable *in vitro* quality.

Table 1: Day 0 Post-Thaw *In Vitro* Quality of PR Plasma; Mean (SD); N=33

Parameter	Mean (SD)
FVIII (IU/mL)	0.83 (0.18)
FVII (IU/mL)	0.87 (0.19)
FV (IU/mL)	1.01 (0.21)
Fibrinogen (g/L)	2.53 (0.56)
PT (sec)	15.1 (0.8)
Protein S (IU/mL)	0.83 (0.15)
Alpha2-Antiplasmin (IU/mL)	1.02 (0.12)
ADAMTS-13 (IU/mL)	0.93 (0.12)

Plasmas Treated Fresh or Previously Frozen: Which Impact on Their Quality?

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BACKGROUND: Two studies were conducted by the French Blood Establishment (EFS) in Bourgogne Franche-Comté and Grand Est on plasma issued from whole blood (WB) to validate the amotosalen and UVA treatment (INTERCEPT Blood System (IBS)) of fresh plasma or previously frozen plasma.

AIMS: We compared the results of two studies intended to assess the quality of plasmas treated-with IBS, fresh or previously frozen.

METHODS: Both studies evaluated the quality of 5 WB plasmas, pooled and separated in 2 bags, treated with IBS and divided in 3 final bags for storage at ≤-25°C. In the first study, plasmas were treated fresh and frozen after IBS treatment within 18-20 hours from collection. For the second study, plasmas were frozen within 24 hours from collection, stored at ≤-25°C for at least 30 weeks, thawed, treated with IBS, frozen and stored at ≤-25°C. In this comparison, we used the analyses made at the same time in both studies: before treatment, after 14 days (d) from treatment and 1 year after collection. The evaluation of the quality of the plasmas was done at the end of each storage time and included biochemical analyses, coagulation capacity (activation and inhibition) and activation of the complement. Statistical comparisons were made between the two groups only, to validate or not the comparison (multiple comparisons one-way ANOVA, $p<0.05$*, $p<0.01$**, $p<0.001$***).

RESULTS: In both studies, using fresh and previously frozen plasmas, fibrinogen and FVIII decreased after IBS treatment and remained stable through the year of storage, within the European (EDQM) and French (ANSM) acceptance criteria. Fibrinogen was higher in the previously frozen plasma study after 14d of treatment. Same observation in the second study for FVIII, with higher concentration after 14d and 1 year of treatment. The total thrombin generation remained stable in both studies through the year of storage but with less thrombin generated in previously frozen plasmas. The peak of thrombin generated was twice higher in fresh plasma than previously frozen plasma at each time of analyses. Same observation with the velocity index, which was significantly higher in fresh plasma.

SUMMARY/CONCLUSIONS: Fresh plasmas and previously frozen plasmas present equivalent quality for biochemical parameters after IBS treatment and storage. Thrombin generation was slightly reduced but remained acceptable in previously frozen plasma study with a slower thrombin generation. As a conclusion, plasmas treated with IBS, fresh or previously frozen, present interesting characteristics and acceptable quality parameters. It shows that both protocols of treatment can be used according to the demand and availability of each type of plasma.

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	Fresh plasma		Previously frozen plasma	
	Before trt year	**14d after trt 1**	**Before trt year**	**14d after trt 1**
Fibrinogen (g/L)	2.6±0.2 2.4±0.3	2.2±0.2	2.7±0.2 2.4±0.1	2.4±0.1**
FVIII (IU/mL)	100.9±14.7 59.7±8.7	67.2±12.3	109.9±10.6 77.8±9.1***	80.2±8.5***
Quantity of thrombin generated (ETP) (nM thrombin.min)	1547.7±113.6 1519.2±117.3	1537.1±125.7	1281.8±219.6*** 1168.6±198.7***	1479.9±172.0
Peak of thrombin generation (nM thrombin)	316.2±36.7 243.8±34.7	246.5±40.9	109.2±25.4*** 103.4±29.7***	124.8±27.6***
Velocity of thrombin generation (nM thrombin.min)	131.5±31.7 72.9±22.2	71.5±20.9	24.8±1.3*** 29.1±3.2***	26.8±1.9***

Preserved Fibrinogen Recovery and Stability of Low Plasma Volume Pathogen Reduced Cryoprecipitated Fibrinogen Complex

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BACKGROUND: Cryoprecipitated Anti-Haemophilic Factor (CRYO-AHF) is enriched for fibrinogen, Factor VIII (FVIII), von Willebrand Factor (VWF), Factor XIII (FXIII) and fibronectin, but has short post-thaw shelf-life (4-6 hours) due to an anticipated heightened risk of transfusion-transmitted infection (TTI). Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC), manufactured from amotosalen/UVA treated plasma (PR plasma), is a fibrinogen supplementation option with a 5-day post-thaw shelf-life at room temperature and reduced TTI risk. PRCFC contains fibrinogen, FXIII, VWF and other key clotting factors required for clot strength and hemostasis in patients with massive hemorrhage associated with fibrinogen deficiency. PRCFC is prepared from 585-650 mL PR plasma, cryoprecipitated and resuspended in a final volume of 60-100 mL. To evaluate lower plasma input, leukocyte-reduced fresh frozen plasma (FFP-LR480), a plasma product used in Japan, was investigated.

AIMS: To evaluate fibrinogen retention and coagulation factor content at 5-days post-thaw in PRCFC prepared from 480 mL of previously frozen apheresis FFP treated with amotosalen and UVA then cryoprecipitated to prepare PRCFC at a lower volume compared to conventional PRCFC.

METHODS: Previously frozen apheresis FFP was thawed at 37°C and pooled to prepare 6 replicates (two O and 4 non-O blood types) at a volume of 480 mL. Pooled plasma was treated with amotosalen/UVA. After treatment, the plasma was kept at -20°C until fully frozen. The frozen PR plasma was transferred to 4°C until sufficiently thawed, centrifuged at 4°C to pellet the cryoprecipitate. The Pathogen Reduced Plasma, Cryoprecipitate Reduced (PRPCR) was removed leaving 50 mL residual volume. PRCFC was resuspended in the residual PRPCR and stored at -20°C. The prepared PRCFC was thawed at 37°C, sampled immediately post thaw, stored at 22°C without agitation and sampled at Day-5 post thaw. Fibrinogen activity was measured by the Clauss assay using a commercial coagulation analyzer. FVIII and VWF activity and FXIII antigen were also measured.

RESULTS: Baseline plasma pools were measured for fibrinogen activity concentrations (319 ± 30 mg/dL), fibrinogen content (1530 ± 142 mg), and FVIII activity (109 ± 13 IU/dL). Amotosalen/UVA -treated plasma showed reduced fibrinogen activity (261 ± 40 mg/dL) compared with baseline. Immediately post-thaw, PRCFC exhibited higher fibrinogen activity (1151 ± 123 mg/dL), and other coagulation factor activities for FVIII (245 ± 34 IU/dL), VWF (365 ± 132 IU/dL), and FXIII antigen (364 ± 50%). Fibrinogen content (581 ± 48 mg) was also measured immediately post thaw. At 5-days postthaw, PRCFC demonstrated modest declines in fibrinogen activity (1053 ± 115 mg/dL), fibrinogen content (532 ± 47 mg), FVIII activity (229 ± 24 IU/dL), VWF activity (313 ± 111 IU/dL) and FXIII antigen (346 ± 24%).

SUMMARY/CONCLUSIONS: Low-volume PRCFC produced from low-volume PR plasma provided substantially higher concentrations of fibrinogen activity and other key coagulation factors compared to plasma. PRCFC achieved >40% recovery (42–62%) of fibrinogen content compared to PR plasma and retained an average of 91% (86–97%) fibrinogen content following post-thaw storage. Collectively, these findings demonstrate that PRCFC produced from FFP-LR480 is a concentrated source of fibrinogen and other key coagulation factors with minimal loss, indicating stability at 5-days post-thaw.

The INTERCEPT Blood System for 7 day storage of platelets is not approved in the US.

Pathogen Reduced Cryoprecipitated Fibrinogen Complex (INTERCEPT® Fibrinogen Complex) manufactured using the INTERCEPT Blood System for Cryoprecipitation is only approved in the United States. INTERCEPT Fibrinogen Complex may be stored at room temperature for five days, post-thaw. In the US, cryoprecipitated AHF manufactured from INTERCEPT® Plasma must be transfused within six hours of thaw.

Notes

Notes

INTERCEPT REGULATORY APPROVALS

Canada (Health Canada)
2016 (plasma), 2018 (platelets)

Brazil (ANVISA)
2015 (platelets and plasma)

United States (FDA)
2014 (platelets and plasma)

Mexico (COFEPRIS)
2014 (platelets and plasma)

Singapore (HSA)
2014 (platelets)

Switzerland (Swissmedic)
2009 (platelets), 2010 (plasma)

Germany (PEI)
2007* (platelets), 2011* (plasma)

France (ANSM)
2003 (platelets), 2006 (plasma)

CE Mark, Class III
2002 (platelets), 2006 (plasma)

*** First blood center marketing authorization approved.**

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Use of INTERCEPT Plasma or Platelets is contraindicated in patients with a history of allergic response to amotosalen or psoralens.
Consult instructions for use for indications, contraindications, warnings, and precautions.