



PROGRAM OF ABSTRACTS

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DATE

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LOCATION

Atlanta, Georgia

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Bacterial Contamination of Platelets with Large Volume Delayed Sample (LVDS) Culture or Amotosalen/UVA Pathogen Reduction (PR)

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BACKGROUND/CASE STUDIES: LVDS culture screening (BACT/ALERT, bioMerieux) was introduced in England (2011), Australian Red Cross Lifeblood (2020), Canadian Blood Services (CBS) (2017), and the American Red Cross (ARC) (2016). Amotosalen/UVA (A/UVA, Cerus) PR was implemented in France (2017), Switzerland (2011), CBS (2024) and the ARC (2018). After FDA approval, manufacturers are required to submit worldwide reports of possible, probable, or definite contaminated products to the FDA MedWatch program.

STUDY DESIGN/METHODS: We searched the FDA MAUDE database for platelet contamination reports related to LVDS [510 (k) # BK050037; BK200472] and A/UVA PR [PMA # BP140143] for 2014-2025 and correlated these with published hemovigilance reports.

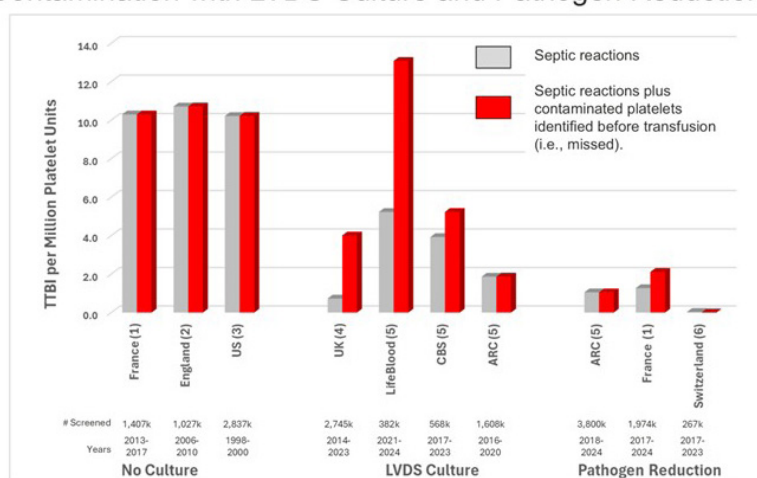
RESULTS/FINDINGS: Three MedWatch reports involving 5 species related to false negative LVDS implicated *Bacillus* spp. (3) and *Staphylococcus* spp. (1) and *Staphylococcus aureus* (1) with or without septic transfusion reactions. Nineteen reports of A/UVA PR platelet contamination involving 10 species implicated *Bacillus* spp. (7) ascribed to reduced spore inactivation; mixed environmental organisms ascribed by the manufacturer to post-illumination contamination (8) (*Acinetobacter* spp., *S. saprophyticus*; *Leclercia* spp., *Serratia* spp., *Enterobacter* spp., *Bacillus* spp., *Klebsiella* spp.); and 4 reports not readily explained with available data (*Klebsiella* spp., *S. haemolyticus*, *E. coli*, *S. ureilyticus*). An estimated 16,104,958 A/UVA PR PCs were produced worldwide between 2014-2025 for an estimated global contamination rate of 1.2 per million PCs. Historical reports prior to LVDS or A/UVA PR suggest a baseline bacterial contamination rate of ~10 per million PCs (**Figure 1**). Contamination and false negative units by LVDS detected before or after transfusion occurred in 4.0; 13.1; 5.2 and 1.9 per million transfusions in the UK (2014-2023), Australia (2021-2024), CBS (2017-2023) and the ARC (2016-2020), respectively. Contaminated A/UVA PR PCs identified before or after transfusion occurred in 1.0, 2.1 and 0.0 per million PCs in the ARC (2018-2024), France (2018-2024), and Switzerland (2017-2023), respectively.

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CONCLUSIONS: Implementation of LVDS and A/UVA PR has reduced but not eliminated the risk of bacterial contamination in PCs, with a lower incidence associated with A/UVA PR. The ARC and CBS converted from LVDS to A/UVA PR. Comparing published data, many false negative LVDS PCs in the hemovigilance literature are not reported to the manufacturer and/or FDA. LVDS and A/UVA PR are both less effective against spore forming organisms and are susceptible to environmental contamination after processing. Potential failure modes leading to post-processing contamination include acquired or manufacturing storage bags defects.

Figure 1: References

Rates of Transfusion Transmitted Bacterial Infection (TTBI) & Contamination with LVDS Culture and Pathogen Reduction



1. Laperche et al. Vox Sanguinis. 2026;1-6. DOI: 10.1111/vox.70199.
2. McDonald et al. Transfusion 2017;57: 1122-31.
3. Kuehnert et al. Transfusion 2001;41: 1493-9.
4. Chugh et al. Vox Sanguinis. 2026; 1-11. DOI: 10.1111/vox.70253.
5. Garcia-Otálora et al. Vox Sanguinis. 2025;120:846-857.
6. SwissMedic Haemovigilance Annual Report 2023.

Prospective Comparison of Pathogen-Reduced and Conventional Cryoprecipitate in Liver Transplantation

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BACKGROUND/CASE STUDIES: Liver transplantation (tx) is associated with severe intraoperative coagulopathy driven by impaired synthetic function and anhepatic-phase fibrinolysis. Cryoprecipitate (cryo) requires on-demand thawing, delaying fibrinogen supplementation during hemorrhage. Pathogen-reduced cryo (PR cryo; INTERCEPT Fibrinogen Complex, Cerus) has a 5-day room-temperature post-thaw shelf life, permitting immediate availability. This hypothesis driven pilot study compares PR cryo with cryo in liver tx to determine the impact on blood component use within 30 days.

STUDY DESIGN/METHODS: This prospective, open-label, cluster-randomized sub-study of the TOP-CLOT trial was conducted at a single academic medical center. Adult liver tx recipients receiving intraoperative cryoprecipitate were eligible. Orders were randomized by month to PR cryo or cryo. The primary outcome was total allogeneic blood component use (RBC, PLT, plasma) within 30 days. Secondary outcomes included component-specific volumes, ROTEM parameters, postoperative fibrinogen, order-to-issue times, length of stay, and adverse events. Multivariable regression adjusted for demographic and surgical covariates.

RESULTS/FINDINGS: Thirty-eight patients were enrolled (19 PR cryo, 19 cryo). Baseline characteristics were balanced with no significant differences (**Table 1**). Total 30-day blood component utilization was higher in the PR cryo cohort on univariate [24 units (IQR 17, 43) vs. 15 (IQR 6, 21); $p=0.021$] and multivariable analysis (IRR 2.00, 95% CI 1.23-3.26; $p=0.003$). Postoperative fibrinogen [179 vs. 194 mg/dL; $p=0.8$], ROTEM parameters were similar. Order-to-issue time was shorter for PR cryo across all orders on univariate analysis [13 min (IQR 7, 27) vs. 30 min (IQR 15, 45); $p<0.001$] but did not retain significance on multivariable adjustment ($\beta=-0.52$ min, 95% CI -1.10 to 0.07; adjusted $p=0.084$).

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CONCLUSIONS: PR cryo demonstrated comparable fibrinogen repletion, ROTEM parameters, and safety to conventional cryoprecipitate in this pilot prospective liver tx study. Although higher blood component utilization was observed in the PR cryo cohort, this finding should be interpreted with caution given the small sample size and potential differences in underlying disease severity.

The lack of a sustained order-to-issue time advantage contrasts with prior PR cryo studies and may reflect the high-volume transfusion requirements characteristic of complex liver tx, where any initial time benefit of pre-thawed products is diluted across subsequent large orders. Additionally, prolonged blood bank-to-operating room transport times may further attenuate this advantage if delivery is delayed until all products are prepared, highlighting that the clinical benefit of PR cryo is likely maximized when it is stored closer to the point of care.

Larger prospective studies are warranted to validate these findings and to optimize the implementation of PR cryo in liver tx.

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Table 1: Baseline Characteristics and Key Outcomes by Cryoprecipitate Type

Characteristic / Outcome	PR Cryo (N = 19)	Cryo (N = 19)	p-value ¹
BASELINE CHARACTERISTICS			
Median Age, years (IQR)	60 (47–68)	52 (49–62)	0.2
Sex — n (%)			0.7
Female	8 (42%)	9 (47%)	
Male	11 (58%)	10 (53%)	
Race — n (%)			0.5
Asian	2 (11%)	0 (0%)	
Black or African American	4 (21%)	2 (11%)	
White	8 (42%)	8 (42%)	
Other / Unknown	5 (26%)	9 (47%)	
Ethnicity — n (%)			0.7
Hispanic or Latino	3 (16%)	6 (32%)	
Not Hispanic or Latino	15 (79%)	12 (63%)	
Unknown / Declined	1 (5.3%)	1 (5.3%)	
ASA physical status — n (%)			0.7
III	3 (16%)	6 (32%)	
IV	15 (79%)	12 (63%)	
V	1 (5.3%)	1 (5.3%)	
Cause of liver disease — n (%)			0.8
Alcohol	7 (37%)	9 (47%)	
Cancer	3 (16%)	1 (5.3%)	
Metabolic (NASH)	2 (11%)	3 (16%)	
Other	7 (37%)	6 (32%)	
Donor type — n (%)			0.6
Donation after brain death (DBD)	13 (68%)	16 (84%)	
Donation after cardiac death (DCD)	3 (16%)	2 (11%)	
Living related	3 (16%)	1 (5.3%)	
Median MELD 3.0 (IQR)	23 (12–31)	18 (15–24)	0.6
Normothermic machine perfusion pump use — n (%)	5 (26%)	5 (26%)	>0.9
PREOPERATIVE LABORATORY TESTING — median (IQR)			
Hemoglobin, g/dL	9.50 (7.70–12.40)	10.90 (7.80–13.70)	0.3
Platelet count, ×10 ³ /μL	68 (45–128)	76 (49–101)	0.8
Albumin, g/dL	2.90 (2.10–3.80)	3.30 (2.70–3.50)	0.2
INTRAOPERATIVE VISCOELASTIC TESTING — median (IQR)			
First intraoperative EXTEM A10 (mm)	38 (31–39)	36 (25–45)	>0.9
First intraoperative FIBTEM A10 (mm)	9.0 (5.0–10.0)	7.0 (6.0–14.0)	0.4
First intraoperative EXTEM CT (s)	71 (65–83)	63 (56–79)	0.14
OUTCOME MEASURES			
TRANSFUSIONS WITHIN 30 DAYS — median (IQR)			
Total components	24 (17–43)	15 (6–21)	0.021 [‡]
RBC units	13 (9–20)	7 (4–10)	0.025
Platelet units	2 (1–5)	1 (0–2)	0.079
Plasma units	11 (6–19)	5 (2–7)	0.013
Fibrinogen replacement doses	3 (2–4)	2 (2–5)	0.4
FIBRINOGEN REPLETION — median (IQR)			
Fibrinogen, postoperative (mg/dL)	179 (167–225)	194 (155–206)	0.8
ADVERSE EVENTS — n (%)			
Thrombotic events	1 (5.3%)	1 (5.3%)	>0.9
Surgical re-exploration	6 (32%)	5 (26%)	0.7
In-hospital death	0 (0%)	1 (5.3%)	>0.9
Need for ventilator after surgery	14 (93%)	14 (93%)	>0.9
Time on ventilator (days); median (IQR)	0.80 (0.50–1.60)	0.65 (0.50–1.30)	0.5
LENGTH OF STAY — median (IQR)			
Hospital LOS (days)	10 (8–15)	10 (8–12)	0.8
OR LOS (hours)	11.1 (9.6–12.5)	10.7 (9.8–12.5)	0.8
ICU LOS (days)	3.0 (2.0–3.8)	2.2 (1.9–3.7)	0.4
PRODUCT AVAILABILITY — median (IQR)			
Order → issue, cryo orders (min)	13 (7–27)	30 (15–45)	<0.001 [†]

¹ Fisher's exact test, Wilcoxon rank sum test; Pearson's Chi-squared test[‡] multivariable analysis (IRR 2.00, 95% CI 1.23–3.26; p=0.003)[†] multivariable adjustment (β=−0.52 min, 95% CI −1.10 to 0.07; p=0.084)

Assessment of Process Performance and Product Quality When Applying a Novel Illumination Device for Pathogen Reduction of Platelets

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BACKGROUND/CASE STUDIES: Ensuring the microbiological safety of platelet concentrates is a central objective in transfusion medicine. To mitigate the risk of transfusion-transmitted infections, the Central Institute for Blood Transfusion and Immunology, Innsbruck, Austria has implemented the amotosalen-based pathogen inactivation process since 2013. A newly developed illumination device, the INT200 Illuminator (Cerus Corporation), was introduced into routine operation one year ago within the amotosalen-based pathogen inactivation process. This study examines operational performance and product quality associated with the use of this novel device.

STUDY DESIGN/METHODS: Apheresis platelet (AP) and pooled platelet (PP) concentrates were subjected to routine quality control from April 2025 to April 2026 that underwent pathogen-reduction using the INT200 following the manufacturer's instructions. Process related variables included UV dose delivery, illumination time, and device reliability. At the beginning of storage AP/PP were assessed for platelet counts and residual cells (n=120 each) and at the end of shelf life for metabolic parameters (n=34 AP, n=31 PP) as well as for residual amotosalen (n=29) according to EDQM quality criteria.

RESULTS/FINDINGS: During this 1-year observation period, the INT200 delivered UV doses within the predefined tolerance range, illumination times were consistent and the device was reliable. Median platelet counts after treatment were 2.85 (IQR $2.59 - 3.16$) $\times 10^{11}$ platelets/unit for AP and 2.55 ($2.30 - 3.23$) $\times 10^{11}$ platelets/unit for PP. For all products, platelets/unit were $\geq 2 \times 10^{11}$ as required by the EDQM blood guide. Residual leucocytes were 0.03 ($0.00 - 0.06$) $\times 10^6$ per unit and residual erythrocytes were 0.003 ($0.000 - 0.004$) $\times 10^{10}$ per unit for AP and 0.07 ($0.03 - 0.18$) $\times 10^6$ per unit and 0.003 ($0.003 - 0.005$) $\times 10^{10}$ per unit for PP, respectively. At the end of shelf life at day 7.5 ($7.0 - 8.0$) for AP and day 7.0 ($7.0 - 7.0$) for PP, pH was 7.0 ($6.91 - 7.05$) for AP and 6.99 ($6.91 - 7.07$) for PP. Aerobic/anaerobic microbial testing results were all negative for AP/PP. Glucose levels were 51.00 (IQR $28.75 - 60.75$) mg/dL for PP (n=24), however for some PP (n=5) levels were below detectability threshold. Swirling was observed in all products at beginning and end of storage. Residual amotosalen was 0.21 ($0.16 - 0.24$) $\mu\text{mol/L}$ for AP/PP.

CONCLUSIONS: The INT200 device performed within its specified operational parameters and supported the production of pathogen reduced platelet concentrates meeting established quality standards. The observed process consistency and product quality characteristics indicate that the device is suitable for integration into routine pathogen reduction workflows. Further post implementation monitoring may help characterize long term performance in diverse operational settings.

***In Vitro* Evaluation of Trima Platelets in 100% Plasma Prepared with Pathogen Reduction using an LED Illuminator**

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BACKGROUND/CASE STUDIES: The INTERCEPT® Blood System for Platelets pathogen reduction technology (PRT), using amotosalen and UVA light, is FDA approved for the *ex vivo* preparation of pathogen-reduced platelet components (PCs) using the INT100 Illuminator. The aim of this study was to evaluate the *in vitro* platelet function of apheresis PCs in 100% plasma prepared with PRT and illuminated with the INTERCEPT LED (INT200, Test) Illuminator compared to PCs illuminated with the INT100 (Control) Illuminator. The INTERCEPT process with the INT200 is in development and not FDA approved.

STUDY DESIGN/METHODS: This was a prospective, multi-center, open-label, pool-and-split, *in vitro* study with PCs from healthy volunteer donors. The study compared 67 Test and Control PCs stored through 5 days. Input PCs contained $3.3\text{--}7.9 \times 10^{11}$ platelets in a volume of 267–420mL. Test and Control PCs were PRT treated using FDA-approved Small Volume, Large Volume, or Dual Storage INTERCEPT Processing Sets. Test PCs were illuminated with the INT200 Illuminator and Control PCs with the INT100 Illuminator. PCs were stored at 22 ± 2 °C with continuous agitation. *In vitro* platelet physical and metabolic characteristics were evaluated. Primary endpoints were pH > 6.2 (95% of units/95% confidence), platelet dose post-PRT and at Day 5 $> 3.0 \times 10^{11}$, and platelet yield retention post-PRT $> 80\%$ (95% of units/75% confidence).

RESULTS/FINDINGS: All primary endpoints were met. All Test PCs had a pH_{22°C} ≥ 6.2 on Day 5 and all Test PCs had a platelet yield retention $\geq 80\%$ post-PRT. 96.2% of Test PCs met the $\geq 3.0 \times 10^{11}$ platelet dose criterion after PRT and 90.6% met on Day 5 (range: 2.6 to 6.0×10^{11} platelets). Parameters indicative of platelet metabolism (pH, ATP, glucose, lactate) and functional characteristics (MPV, morphology score) were well maintained and there was no statistically significant difference between Test and Control. Test PCs had statistically higher HSR than Control, likely attributable to the high variability of the assay. All other parameters were not statistically different. Additionally, the level of platelet activation measured by P-selectin expression was within expected ranges.

CONCLUSIONS: Trima apheresis PCs in 100% plasma, undergoing PRT treatment with amotosalen/UVA utilizing the LED Illuminator and stored for 5 days retained *in vitro* metabolic and functional properties. Additionally, there were no significant differences in *in vitro* platelet function between INT200- and INT100-illuminated platelets.

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Table 1: Day 5 *In Vitro* Summary (Mean $\pm$ SD) (n=67)

	Control (INT100)	Test (INT200)
Component Volume (mL)	281 $\pm$ 68 ^a	277 $\pm$ 67 ^b
Platelet Count ($\times 10^3$ cells/ μ L)	1299 $\pm$ 220 ^d	1294 $\pm$ 215 ^c
Platelet Dose ($\times 10^{11}$ cells)	3.8 $\pm$ 0.8 ^d	3.7 $\pm$ 0.7 ^c
pH22°C	7.3 $\pm$ 0.1	7.3 $\pm$ 0.1
Supernatant Glucose (mmol/ 10^{12} cells)	9.9 $\pm$ 2.8 ^d	10.0 $\pm$ 2.8 ^c
Supernatant Lactate (mmol/ 10^{12} cells)	7.4 $\pm$ 1.3 ^d	7.3 $\pm$ 1.3 ^c
Total ATP (nmol/ $\times 10^8$ cells)	3.7 $\pm$ 0.6 ^d	3.7 $\pm$ 0.6 ^c
Morphology	241 $\pm$ 29	244 $\pm$ 30
Extent of Shape Change (%)	20.1 $\pm$ 3.9	20.1 $\pm$ 4.2
Hypotonic Shock Response (%)	46.5 $\pm$ 11.2	52.3 $\pm$ 11.6*
Supernatant LDH (U/ 10^{12} cells)	169 $\pm$ 58 ^d	162 $\pm$ 40 ^c
Baseline Adjusted Proportional LDH (%)	2.3 $\pm$ 2.2	2.0 $\pm$ 1.7 ^d
P-selectin (CD62P expression, %)	38.0 $\pm$ 9.0 ^d	37.8 $\pm$ 8.8 ^c
Lactadherin positive (%)	2.7 $\pm$ 1.1 ^e	2.7 $\pm$ 1.0 ^c

* Statistically significant difference ($p < 0.05$) between Test and Control.

a N=78, b 79, c N=64, d n=66, e N=65

Note: INTERCEPT process is not FDA approved with the INT200.

***In Vitro* Evaluation of Amicus Platelets in 65% PAS Prepared with Pathogen Reduction with LED Illuminator**

Bethany Brown¹, Adrienne Karpel², Susanne Marschner³, Michael S. Wellington¹, Cheryl Heber², Caroline Leite³, Perla Hadjuk², David Buesing³, Jamie Genthe⁴, Anna Erickson⁴

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BACKGROUND/CASE STUDIES: The INTERCEPT® Blood System for Platelets pathogen reduction technology (PRT), using amotosalen and UVA light, is FDA approved for the *ex vivo* preparation of pathogen-reduced platelet components (PCs) using the INT100 Illuminator. The aim of this study was to evaluate the *in vitro* platelet function of apheresis PCs in 65% PAS-3/35% plasma prepared with PRT and illuminated with the INTERCEPT LED (INT200, Test) Illuminator compared to PCs illuminated with the INT100 (Control) Illuminator. The INTERCEPT process with the INT200 is in development and not FDA approved.

STUDY DESIGN/METHODS: This was a prospective, multi-center, open-label, pool-and-split, *in vitro* study with PCs from healthy volunteer donors. The study compared 68 Test and Control PCs stored through 5 days. Input PCs contained 3.4 to 7.3×10^{11} platelets in a volume of 287 to 420 mL. Test and Control PCs were PRT treated using Small Volume, Large Volume, or Dual Storage INTERCEPT processing sets. Test PCs were illuminated with the INT200 Illuminator and Control PCs with the INT100 Illuminator. Test and Control PCs were stored for 5 days at $22^\circ\text{C} \pm 2^\circ\text{C}$ with continuous agitation. *In vitro* platelet physical and metabolic characteristics were evaluated at Day 5. Primary endpoints were day 5 $\text{pH}_{22^\circ\text{C}} > 6.2$ (95% of units/95% confidence), platelet dose post-Intercept treatment $> 3.0 \times 10^{11}$ and platelet yield retention post-Intercept treatment $> 85\%$ (95% of units/75% confidence).

RESULTS/FINDINGS: All (100%) PCs retained a mean platelet dose of $\geq 3.0 \times 10^{11}$ platelets/component post-PRT and had a platelet yield retention of $\geq 85\%$. At the end of storage, Test PCs had a dose range of 2.7 - 5.9×10^{11} platelets and majority (64/68, 94.1%) retained a platelet dose of $\geq 3.0 \times 10^{11}$ platelets/component on Day 5, and all (68/68, 100%) Test PCs had a $\text{pH} \geq 6.2$. Additionally, there was retention of *in vitro* metabolic and functional properties consistent with post-transfusion viability. Although, Test PCs had higher lactadherin expression (phosphatidylserine) than Control PCs, the means were within a 5% difference which is not physiologically relevant. All other parameters were not statistically different. Parameters indicative of platelet metabolism (pH , ATP, glucose, and lactate) and functional characteristics (MPV, morphology score) were comparable. Additionally, the level of platelet activation measured by P-selectin expression was similar and not excessive.

CONCLUSIONS: Amicus apheresis PCs in 65% PAS-3/35% plasma, undergoing PRT treatment with amotosalen/UVA utilizing the LED Illuminator and stored for 5 days retained *in vitro* metabolic and functional properties relevant to *in vivo* functionality. The INT200 illuminated platelets were similar to INT100-illuminated platelets.

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Table 1: End of Storage (Day 5) *In Vitro* Summary (Mean $\pm$ SD) (n=68)

	Control (INT100)	Test (INT200)
Component Volume (mL) ^a	299 $\pm$ 62	300 $\pm$ 61
Platelet Count ($\times 10^3$ cells/ μ L)	1287 $\pm$ 182	1274 $\pm$ 178
Platelet Dose ($\times 10^{11}$ cells)	3.9 $\pm$ 0.8	3.9 $\pm$ 0.8
pH22°C	7.0 $\pm$ 0.1	7.0 $\pm$ 0.1
Supernatant Glucose (mmol/ 10^{12} cells)	1.1 $\pm$ 0.7	1.1 $\pm$ 0.7
Supernatant Lactate (mmol/ 10^{12} cells)	7.8 $\pm$ 1.2	7.8 $\pm$ 1.2
Total ATP (nmol/ $\times 10^8$ cells)	3.1 $\pm$ 0.6	3.1 $\pm$ 0.6
Morphology	289 $\pm$ 31	287 $\pm$ 31
Extent of Shape Change (%)	16.9 $\pm$ 4.5	17.1 $\pm$ 5.1
Hypotonic Shock Response (%)	42.2 $\pm$ 10.1	41.2 $\pm$ 11.0
Supernatant LDH (U/ 10^{12} cells) ^b	155 $\pm$ 83	162 $\pm$ 88
Baseline Adjusted Proportional LDH (%) ^b	3.2 $\pm$ 1.6	3.4 $\pm$ 1.6
P-selectin (CD62P expression, %)	55.7 $\pm$ 13.8	55.3 $\pm$ 13.7
Lactadherin positive (%)	9.6 $\pm$ 4.9	10.1 $\pm$ 5.1*

* Statistically significant difference ($p < 0.05$) between Test and Control.

Note: INTERCEPT process is not FDA approved with the INT200. a N=74, b N=67

***In Vivo* Recovery and Survival Apheresis Platelets in 100% Plasma Treated with Pathogen Reduction with LED Illuminator**

Jamie Genthe¹, Moritz Stolla², Bethany Brown³, S. Lawrence Bailey², Michael S. Wellington³, Anna Erickson¹

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BACKGROUND/CASE STUDIES: The INTERCEPT® Blood System for Platelets pathogen reduction technology (PRT) using amotosalen and UVA light is FDA approved for the *ex vivo* preparation of pathogen-reduced platelet components (PCs) using the INT100 Illuminator. The aim of this study was to evaluate the *in vivo* recovery and survival of apheresis PCs in 100% plasma prepared with PRT and illuminated with the INTERCEPT LED (INT200) Illuminator. The INTERCEPT process with the INT200 is in development and not FDA approved.

STUDY DESIGN/METHODS: This trial was a single arm design comparing the recovery and survival of stored Test platelets against fresh Control platelets. PRT processed platelets (Test) from 24 subjects were prepared for radiolabeling following Variant 1 of BEST 4.2.1 method. The study population comprised healthy adult subjects who met the FDA, AABB, and site-specific research donor eligibility criteria for allogeneic and plateletpheresis donor qualifications. Apheresis platelets were collected in 100% plasma on the Trima Accel®. PCs containing 4.0 to 5.2×10^{11} platelets in 322 to 374 mL of plasma were processed using the INTERCEPT Large Volume Platelet Processing Set. The INTERCEPT treatment process began on either the day of collection (Day 0) or the day following collection (Day 1); illumination started within 24 hours after the end of collection. Test PCs were stored for 5 days, from day of collection, in 100% plasma.

RESULTS/FINDINGS: Stored PRT PCs demonstrated a mean post-transfusion recovery of $52.8 \pm 11.4\%$ versus $64.2 \pm 11.7\%$ for the fresh Control (**Table 1**) and met the FDA criterion for the lower bound $\geq 0.0\%$ of the two-sided 95% CI for 0.66 of the Control (T-ΔC 95% CI [7.7, 13.3]). PRT PCs demonstrated a mean post-transfusion survival of 157.4 ± 20.1 hours versus 207.3 ± 27.1 hours for the fresh Control (Table 1) and met the FDA criterion for the lower bound of the two-sided 95% CI of ≥ 0.0 hours for 0.58 of the Control (T-ΔC 95% CI [29.0, 45.3]). Following PRT, PCs had a platelet dose of $4.2 \pm 0.5 \times 10^{11}$ platelets and a yield of $89 \pm 7\%$. On Day 5 the PCs had a pH_{22°C} of 7.3 ± 0.1 . Additionally, the components retained levels of glucose and ATP indicating sufficient mitochondrial respiration.

CONCLUSIONS: PRT platelets illuminated with the LED Illuminator retained sufficient *in vitro* and functional characteristics consistent with *in vivo* viability. Compared with fresh Control platelets, the *in vivo* recovery and survival of 5-day stored PRT platelets met the FDA criterion for non-inferiority.

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Table 1: *In Vivo* Recovery and Survival of Day 5 PRT Platelets Compared to Fresh Control (n=24)

	Test	Control	T- Δ C ^a
Recovery (%)			
Mean $\pm$ SD	52.8 $\pm$ 11.4	64.2 $\pm$ 11.7	10.5 $\pm$ 6.6
Min to Max	32.2 to 79.8	47.9 to 87.7	-2.3 to 27.5
[95% CI for Mean]	[48.0, 57.6]	[59.2, 69.1]	[7.7d, 13.3]
Survival (Hours)			
Mean $\pm$ SD	157.4 $\pm$ 20.1	207.3 $\pm$ 27.1	37.1 $\pm$ 19.4
Min to Max	108.1 to 198.6	129.3 to 242.2	-13.1 to 67.2
[95% CI for Mean]	[148.9, 165.9]	[195.9, 218.8]	[29.0d, 45.3]

a. $T-\Delta C = (\text{Test}) - (\Delta \times \text{Control})$, where $\Delta = 0.66$ for recovery and 0.58 for survival.

b. Lower bound of the 95% CI ≥ 0 designates non-inferiority was achieved.

INT200 LED Illuminator for Photochemical Inactivation of Bacteria in Platelet Concentrates

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BACKGROUND/CASE STUDIES: The INTERCEPT® Blood System for Platelets uses amotosalen and ultraviolet A (UVA) light to inactivate pathogens in donor platelet concentrates (PC). The intended use of the INTERCEPT Blood System for Platelets is the *ex vivo* pathogen-reduction of PC in order to reduce the risk of transfusion-transmitted infection (TTI), including sepsis. The currently approved illuminator (INT100) uses bulbs to emit UVA light. Cerus has developed a new LED-based illuminator (INT200) as a planned replacement to deliver a controlled dose of UVA light at a specified intensity and duration.

STUDY DESIGN/METHODS: The objective of these studies was to assess the performance of the INT200 Illuminator via the evaluation of bacterial inactivation levels achieved in PC at post-illumination.

Inactivation efficacy was assessed for Gram-positive and Gram-negative bacteria using high bacterial input titer (5.6 to 8.1 log cfu/mL). Bacteria selected for inactivation studies included bacteria known to be causative agents of or represent a potential risk of transfusion transmitted infections. Studies were performed with apheresis PC resuspended in ~332.5 mL of 35% plasma/65% PAS-3 or 100% plasma (nominal conditions), or ~420 mL of 47% plasma/53% PAS-3 or 100% plasma (guardband conditions). Amotosalen was added to each contaminated PC unit which was then illuminated using the INT200 Illuminator. Samples were taken immediately pre- and post-illumination and were analyzed for bacterial titer.

RESULTS/FINDINGS: Comparable robust inactivation (4 log cfu/mL or more) was observed across platelet matrices and volumes. Some bacteria exhibited lower than 4 log reduction and some Gram-negative bacteria had lower levels of inactivation in guardband conditions.

CONCLUSIONS: Amotosalen/UVA treatment with the INT200 Illuminator consistently inactivated high titers of bacteria under nominal and guardband conditions for plasma and volume. Overall, these results demonstrate that the INT200 Illuminator can provide robust performance against a variety of transfusion-relevant bacterial strains.

Development of the INT200 Illuminator for Photochemical Inactivation of Viruses and Parasites in Platelet Concentrates

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BACKGROUND/CASE STUDIES: 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 (PC). The intended use of the INTERCEPT Blood System for Platelets is the *ex vivo* pathogen-reduction of PC in order to reduce the risk of transfusion-transmitted infection (TTI), including sepsis. The currently approved commercial illuminator (INT100) uses bulbs to emit UVA light. Cerus has developed a new LED-based illuminator (INT200) as a planned replacement to deliver a controlled dose of UVA light at a specified intensity and duration.

STUDY DESIGN/METHODS: The objective of these studies was to assess the performance of the INT200 Illuminator via the evaluation of viral and parasite inactivation levels achieved in PC.

Inactivation efficacy was assessed for enveloped and non-enveloped viruses, and parasites, using high input titers (4.1 to 7.4 log pfu/mL or TCID 50 /mL). Pathogens selected for inactivation studies included pathogens known to be causative agents of or represent a potential risk of transfusion transmitted infections, or accepted model organisms. Studies were performed with apheresis PC resuspended in ~332.5 mL of 35% plasma/65% PAS-3 or 100% plasma (nominal conditions), or ~420 mL of 47% plasma/53% PAS-3 or 100% plasma (guardband conditions). Amotosalen was added to each contaminated PC unit which was then illuminated using the INT200 Illuminator. Samples were taken immediately pre- and post-illumination and were analyzed for viral and parasite titer.

RESULTS/FINDINGS: For all viruses and parasites tested with the exception of small non-enveloped viruses known to be resistant to inactivation, robust inactivation (4 log pfu/mL or TCID 50 /mL or more) was observed across platelet matrices and volume. Some non-enveloped viruses had lower levels of inactivation in platelets in 100% plasma or under guardband conditions in platelets in PAS, but these organisms still exhibited >4 log pfu/mL reduction after amotosalen/UVA treatment.

CONCLUSIONS: Amotosalen/UVA treatment with the INT200 Illuminator consistently inactivated high titers of a broad spectrum of viruses and parasites under nominal and guardband conditions for plasma and volume. Overall, these results demonstrate that the INT200 Illuminator can provide robust performance against a variety of transfusion-relevant parasites and viral strains.

A Time/Motion Study to Assess Irradiated and Pathogen Reduced Platelet Component Inventory Management and Workflow at a Large Academic Medical Center in the Mid-South U.S.

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BACKGROUND/CASE STUDIES: Transfusion-associated graft-versus-host disease (TA-GVHD) is a rare but often fatal complication caused by residual donor T cells. Irradiation and amotosalen-UVA pathogen reduction technology (PRT) are FDA-approved methods to mitigate TA-GVHD risk in platelet components (PCs). Irradiation practices in the U.S. vary, including indication-based and universal approaches, with products irradiated either on-site or by suppliers. We compared workflow and inventory management of large volume delayed sampled (LVDS), irradiated PCs versus pathogen-reduced (PR) PCs in a large academic hospital blood bank, hypothesizing that PRT simplifies operations and improves platelet availability.

STUDY DESIGN/METHODS: A time-and-motion analysis was conducted to evaluate workflow efficiency and inventory management of LVDS irradiated and PR PC at a hospital maintaining a dual platelet inventory. The study site performs on-site, on-demand irradiation of platelet units. Direct observation and process mapping were used to characterize each step in the handling, irradiation, modification, and issuance of platelet components.

RESULTS/FINDINGS: LVDS PC were irradiated on demand, typically one unit at a time upon receipt of product send orders. Preparation of an irradiated LVDS PC required a mean of 17.2 minutes per unit, compared to 9.1 minutes for a PR PC, representing a time savings of 8.1 minutes per unit (**Table 1**), including the six additional irradiation-related modification and relabeling steps. Completion of an order for an irradiated LVDS PC involved 12 process steps, whereas for PR PCs 6 steps were involved. PR PCs were received into hospital inventory without additional processing steps required. The mean platelet age at issue was 6.1 days for irradiated LVDS PCs and 4.3 days for PR PCs.

CONCLUSIONS: PR PCs provide an alternative to irradiated PCs that may simplify inventory management and reduce process complexity in a large academic hospital setting. An additional benefit may include reduced risk of transfusing non-irradiated components when TA-GVHD mitigation is indicated.

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Table 1: PC Handling Cycle Time Summary

Process	Cycle Time per Unit		
	PRT	LVDS	Irrad. LVDS
Receive and Store PLT	1.5	1.5	1.5
New Transfuse Order	0.4	0.4	0.4
Obtain PLT	1.8	1.8	1.8
Irradiate PLT (avg.)			6.4
Modify PLT			1.0
Issue PLT	3.9	3.9	3.9
Wait/Idle	1.5	1.5	2.2
Total	9.1	9.1	17.2

*All times in minutes

Two decades of amotosalen/UVA platelet and plasma hemovigilance in Europe

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BACKGROUND/CASE STUDIES: Since 2003, six prospective hemovigilance (HV) studies have evaluated the safety of amotosalen/ultraviolet A (A/UVA)-treated platelet and plasma components in routine use in Europe. This report summarizes the cumulative exposure and transfusion reactions across the full program.

STUDY DESIGN/METHODS: Methods, endpoints and data were extracted from study reports and protocols maintained by the sponsor (Cerus Corporation) and associated publications. Endpoints included total components transfused, total patients transfused, and transfusion reactions (TRs). Results were compared against findings from A/UVA clinical trials and national HV estimates.

RESULTS/FINDINGS: All six HV studies were based on prospective, non-interventional surveillance methods. Consent was not required for collection of de-identified data. Data were collected from 29 hospitals in 15 countries. Across five studies focused on A/UVA platelet components (PCs), 24,972 A/UVA PCs were transfused to 5,240 patients. PC-associated TRs were infrequent. A total of 138 TRs occurred (0.6% per transfusion; 2.5% per patient) in the PC studies. The most common PC-related TRs were febrile non-hemolytic and allergic reactions; 2 TRs were serious. In three studies with A/UVA plasma data, a total of 59,335 A/UVA plasma components were transfused to 9,900 plasma recipients for coagulopathy and therapeutic plasma exchange (TPE). TRs occurred after 43 of 59,335 plasma transfusions (0.01%) in 9,900 patients (0.87%). **(Table)** Most plasma TRs were minor allergic or febrile-hypotensive events. Six TRs were serious including allergic reactions and TACO. On a per-patient basis, patients received a mean of 4.8 ± 9.4 A/UVA PCs and 5.9 ± 11.5 A/UVA plasma components, with wide variability between sites. **(Table)**

CONCLUSIONS: Over more than 22 years of routine clinical use, sponsored HV studies have shown low frequency of acute TRs associated with A/UVA PCs and plasma. TRs were dominated by expected febrile and allergic events, with rare serious reactions and no safety signals for TRALI, TTIs, TA-GVHD, or transfusion-related mortality. These studies did not evaluate efficacy but utilization patterns were a surrogate for efficacy and clinical practice. Per-patient use and transfusion intervals were within ranges observed in controlled clinical studies. TR frequency was comparable to national HV estimates. Limitations include the use of passive surveillance which may underestimate TR frequencies and an inability to perform trend analyses over extended periods. The combined data presented here reaffirm the positive risk-benefit profiles for both A/UVA PCs and plasma with the largest surveillance dataset for A/UVA components compiled to date.

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Table

Study	Years	Platelets					Plasma				
		Units	TRs per unit (%)	Patients	TRs per patient (%)	PCs/ patient, mean $\pm$ SD	Units	TRs per unit (%)	Patients	TRs per patient (%)	Plasma units/ patient, mean $\pm$ SD
HV1	2003-05	5,106	55 (1.1%)	651	42 (6.5%)	7.8 $\pm$ 16.2	—	—	—	—	—
HV2	2005-07	7,437	55 (0.7%)	1,400	39 (2.8%)	5.3 $\pm$ 10.8	—	—	—	—	—
HV3	2006-10	6,632	26 (0.4%)	2,016	23 (1.1%)	3.3 $\pm$ 5.05	—	—	—	—	—
HV4	2007-10	—	—	—	—	—	57,171	41 (0.2%)	9,667	32 (0.3%)	5.9 $\pm$ 10.5
HV5	2013-16	2,373	9 (0.4%)	698	8 (1.1%)	3.4 $\pm$ 4.9	257	0 (0%)	146	0 (0%)	1.76 $\pm$ 1.73
HV6	2019-25	3,424	6 (0.2%)	475	5 (1.1%)	7.2 $\pm$ 9.4	1,907	2 (0.1%)	87	2 (2.3%)	21.9 $\pm$ 50.4
Total (Mean$\pm$SD)		24,972	151 (0.6$\pm$0.4%)	5,240	117 (2.5$\pm$2.3%)	4.8 $\pm$ 9.4	59,335	43 (0.1$\pm$0.1%)	9,900	34 (0.87$\pm$1.3%)	5.9 $\pm$ 11.5

Operational Experience With Amotosalen/UVA Pathogen Reduction for On-Demand Apheresis Platelets in Morelos, Mexico

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BACKGROUND/CASE STUDIES: Amotosalen and ultraviolet A light pathogen reduction (A/UVA PR) reduces TTI and immunological risks in platelet components (PCs) by blocking nucleic acid replication in microorganisms and leukocytes. The technology is used in ~30 countries worldwide. In middle income countries (MIC) blood banks may perform on-demand apheresis collections and manage limited reserve inventories with reduced shelf-life due to bacterial contamination concerns. We describe the evaluation of A/UVA PR by one Mexican blood center as an approach to extend shelf-life and potentially improve the safety of apheresis PCs in a dual inventory system.

STUDY DESIGN/METHODS: This single-center evaluation used routine blood bank production and quality-control data from the Mexican Red Cross in Morelos, Mexico during a pilot A/UVA implementation project for PCs from May 2024 to April 2025. Monthly counts of apheresis PCs prepared with A/UVA or only screened with conventional bacterial culture screening (BCS) were summarized with linked BCS results.

RESULTS/FINDINGS: Apheresis platelets were collected on request for planned surgeries or treatments. One dose from each double-dose apheresis collection was issued immediately for transfusion; the companion dose was either stored for ≤ 3 days without A/UVA PR or was treated with A/UVA PR and stored for up to 7 days. Small-volume (3-4 mL) BCS with early sampling (Day 0) was performed on all units; repeat culturing was performed on the day of transfusion and post-expiry (after Day 7) as a quality-control measure. Of 121 apheresis PCs collected, 36 were A/UVA PR (29.8%); 85 (70.2%) were untreated. The proportion of PCs undergoing A/UVA PR ranged from 7.1% to 56% per month. Among conventional units, 8/82 (9.4%) were BCS-positive at issue (**Table**). No BCS-positive events were identified in A/UVA PR units through the end of shelf-life (0/36). More than 90% of PCs were transfused (mean 93.3 ± 13.0 , A/UVA; mean 92.4 ± 14 , untreated). All PCs with positive BCS results were interdicted before transfusion. None of the A/UVA PCs were associated with adverse events (AEs). Eight patients transfused with conventional PCs had an AE. Of these, 7/8 (87.5%) were mild to moderate allergic reactions. One patient had a mild fever.

CONCLUSIONS: In this routine-use pilot project, A/UVA PR allowed the use of the second dose from double-dose apheresis collections for 7 days without BCS. No BCS positives were detected through the end of shelf-life for the A/UVA PCs. Utilization rates were comparable for both types of PCs. This strategy nonetheless demonstrates the feasibility of adding A/UVA PR for one of 2 apheresis double-dose collections as a strategy to potentially improve PC safety and availability in MIC blood centers with limited inventories.

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Table

Year	2024								2025				Totals
Month (units produced/ screened)	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	
	n	n	n	n	n	n	n	n	n	n	n	n	
A/UVA	2	3	2	1	5	5	3	5	4	2	3	1	36
n (%) BCS+	0	0	0	0	0	0	0	0	0	0	0	0	0
% transf.	100	100	100	100	80	100	100	80	60	100	100	100	93.3
BCS only	9	21	10	11	4	6	3	5	6	2	3	2	82
n (%) BCS+	0	0	3 (30%)	4 (32.2%)	1 (25%)	0	0	0	0	0	0	0	8
% transf.	100	100	70	63.8	75	100	100	100	100	100	100	100	92.4
Total units	11	24	12	12	9	11	6	10	10	4	6	3	118
% A/UVA	18	13	15	7	56	45	50	50	40	50	50	33	36



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Use of INTERCEPT Plasma, Platelets, and Pathogen Reduced Cryoprecipitated Fibrinogen Complex are contraindicated in patients with a history of allergic response to amotosalen or psoralens. Consult package inserts^{1,2,3} for indications, contraindications, warnings, and precautions.

1. The INTERCEPT Blood System for Platelets Package Insert, Cerus Corporation, November 28, 2025. 2. The INTERCEPT Blood System for Cryoprecipitation for the manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Package Insert, Cerus Corporation, August 28, 2024. 3. The INTERCEPT Blood System for Plasma Package Insert, Cerus Corporation, September 6, 2022.