Test Report
Prepared for:
Patrick Pennie
CEO

Emcyte Corporation

18 May 2023

Comparison Testing:

EmCyte
PurePRP® Supraphysiologic 60mL
Platelet Concentrating System

Vs

Cervos
Medical Platelet Separator

Prepared by:
Natalie A. Stephens, Ph.D.
Biofyl Scientific Research
Fort Myers, FL

Study Objective:
The objective of this study was to compare platelet concentrates products prepared using the EmCyte PurePRP® SupraPhysiologic (SP) 60mL device and the Cervos Platelet Separator device.

Study Design:
Up to 120 mL of human whole blood was drawn from each of 8 donors following informed consent. The consent form and blood collection protocols are approved by the WCG Independent Review Board, Study number 1333771 expiration date 20 May 2024. Donors will meet the requirements of the American Association of Blood Banks (AABB), the FDA CBER and the Code of Federal Regulations: 21 CFR 606 and Title 45 Public Welfare – Department of Health and Human Services Part 46 Protection of Human Subjects. There are no specific exclusion criteria, other that the donor be healthy, aged 18 – 55 years. Donors are referenced only by assigned code numbers.

Whole blood was drawn into syringes preloaded with anticoagulant. The final concentrations were 13.3% sodium citrate and 10% ACDA for the PurePRP® SP device and the Cervos Platelet Separator, respectively. Devices were compared in a paired donor design, using a double spin protocol, according to each manufacturer's instructions for use. Platelet concentrate products were evaluated for cell counts and platelet activation immediately post-processing.

Study Parameters:
White Blood Cell, Red Blood Cell and Platelet Concentration
Complete Blood Counts were performed using the Beckman Coulter DxH500 Hematology analyzer for baseline (whole blood) and platelet concentrate products. Counts were performed according to SOP TM-160: Cell Count of Blood and Blood Derivatives: DxH500 Hematology Analyzer.

Platelet Concentration Factor (x baseline)
Platelet concentrations were measured using the DxH500 hematology analyzer for baseline and platelet concentrates. The platelet concentration factor, which is the ratio of the PRP platelet concentration to the baseline platelet concentration, was determined for each product.

WBC, RBC and Platelet Recoveries (%)
WBC and Platelet concentrations were measured using the DxH500 hematology analyzer for baseline and platelet concentrates. Cell recovery, which is the ratio of the total PRP cell count to the total baseline cell count, was determined for each product for both WBC and Platelet parameters.

Total Deliverable Platelets
The total number of deliverable platelets for each concentrate product was calculated using the platelet concentration and the product volume. (PLT concentration x Volume)

Platelet Activation (% p-selectin expression)
P-selection expression was determined by flow cytometry to assess the degree of process-dependent platelet activation. Baseline and platelet concentrate samples were evaluated under resting conditions and following the addition of adenosine diphosphate (ADP) agonist to evaluate platelet function. Testing was conducted according to SOP: TM-003: Cytometric Analysis of the P-Selectin.

Summary of Results:

Platelet concentrates prepared using the EmCyte PurePRP® SP and Cervos Platelet Separator devices were compared in a paired donor study design. Platelet concentrates were prepared using centrifuges with swing bucket rotors by a double spin protocol. For both devices, 60mL of whole blood was centrifuged briefly for the first spin, resulting in substantial red blood cell (RBC) removal and collection of a platelet plasma suspension (PPS). The second spin resulted in separation of platelet poor plasma (PPP) and buffy coat formation. The final platelet-rich plasma product was harvested following removal of the majority of the PPP volume followed by subsequent buffy coat resuspension.

The PurePRP® SP 60mL device has two separate chambers contained in a singular device and utilizes syringes for removal and transfer of plasma during processing. The Cervos Platelet Separator utilizes separate canisters for each centrifugation step and instructs the use of syringes and a threaded rod for PPS and PPP removal after each centrifugation step. For the PurePRP® SP device, buffy coat resuspension is performed by gentle swirling of the device and PRP is harvested using a syringe. For the Cervos Platelet Separator, the buffy coat is resuspended by using a syringe to flush the separator canister and to collect the PRP product.

The mean platelet recovery for the Cervos Platelet Separator was 49%, while the number of total deliverable platelets was 6.3 billion. The mean platelet recovery for the PurePRP® SP device was 94%, which was significantly greater when compared to the Cervos device. Consistent with greater recovery, the number of total deliverable platelets was also substantially higher at approximately 12 billion. The platelet concentration factors were 7.2x in 4.0mL PRP (Cervos) and 7.9x in 7.0mL PRP (PurePRP® SP). This is consistent with the lower recovery rate in the Cervos device as you had to remove significantly more volume in order to achieve a similar concentration factor as the PurePRP® SP. The average final PRP product volumes were 4.0mL for the Cervos Device and 7.0mL for the PurePRP® SP device. The majority of red blood cells were removed during processing for both devices with less than 2% remaining in the final PRP product. Analysis of p-selectin expression of non-activated PRP products indicated there was no significant device-dependent activation during processing using either device. P-selectin analysis also showed a robust platelet response (>95%) to ADP-stimulation in PRP products.

Study Results:

Summary – Hematology of Products (Mean ± SD)

Device	**WBC Concentration** (x 10^6/mL)	**PLT Concentration** (x 10^6/mL)	**RBC Concentration** (x 10^9/mL)
PurePRP® SP	**19.0 ± 4.5**	**1722.4 ± 245.3**	**0.5 ± 0.3**
Cervos	**4.5 ± 2.8**	**1594.0 ± 311**	**0.1 ± 0.1**

Summary – Product Platelet Parameters (Mean ± SD)

Device	**Starting Baseline Volume** (mL)	**PLT Yield** (%)	**Total Deliverable PLTs** (x10^6)	**PLT Concentration Factor** (x baseline)	**PRP Product Volume** (mL)
PurePRP® SP	60	**94 ± 3**	**11970 ± 1520.4**	**7.9 ± 0.5**	**7.0 ± 0.4**
Cervos	60	**49 ± 8**	**6301 ± 1249.9**	**7.2 ± 1.4**	**4.0 ± 0.5**

Summary – Product Platelet Activation (Mean ± SD)

Device	**PLT Activation - Resting** (% p selectin expression)	**PLT Activation - ADP** (% p selectin expression)
PurePRP® SP	**4.8 ± 2.7**	**97.4 ± 0.8**
Cervos	**3.7 ± 2.2**	**97.5 ± 0.7**

Baseline Hematology - PurePRP®-SP
WBC – White Blood Cell; RBC – Red Blood Cell; Hct – Hematocrit; PLT – Platelet

Donor ID	WBC ($x 10^6$/mL)	RBC ($x 10^9$/mL)	Hct (%)	PLT ($x 10^6$/mL)
1	6.8	4.1	34.4	262
2	3.2	3.5	27.8	178
3	6.4	3.4	30.3	225
4	7	3.8	36.2	234
5	9.4	4	34.1	216
6	3	4.2	36.4	197
7	5.4	4	32.1	229
8	4.6	4.1	34.8	203
Average	**5.7**	**3.9**	**33.3**	**218.0**
St Dev	2.1	0.3	3.0	25.7

Baseline Hematology - Cervos
WBC – White Blood Cell; RBC – Red Blood Cell; Hct – Hematocrit; PLT – Platelet

Donor ID	WBC ($x 10^6$/mL)	RBC ($x 10^9$/mL)	Hct (%)	PLT ($x 10^6$/mL)
1	7.4	4.2	35.3	256
2	3.1	3.4	27.7	178
3	6.7	3.5	30.7	233
4	7.3	3.8	36.3	242
5	9.8	4	33.8	226
6	3.2	4.3	37.1	215
7	5.5	4	31.6	227
8	4.7	4.3	36.5	202
Average	**6.0**	**3.9**	**33.6**	**222.4**
St Dev	2.3	0.3	3.3	24.2

Platelet Concentration, Platelet Concentration Factor and Platelet Recovery

Donor ID	**PLT Concentration** (x 10^6/mL)		**PLT Concentration Factor** (x baseline)		**PLT Recovery** (%)	
	PurePRP® SP	Cervos	PurePRP® SP Avg 7.2mL	Cervos Avg 4mL	PurePRP® SP Avg 7.2mL	Cervos Avg 4.0mL
1	2120	1648	8.1	6.4	98%	50%
2	1385	1238	7.8	6.9	94%	41%
3	1636	1262	7.3	5.4	93%	46%
4	1864	1424	8	5.9	96%	39%
5	1569	2206	7.3	9.8	91%	64%
6	1570	1708	8	7.9	95%	48%
7	1986	1735	8.7	7.6	90%	47%
8	1649	1531	8.1	7.6	98%	56%
Average	**1722.4**	**1594.0**	**7.9**	**7.2**	**94%**	**49%**
St Dev	245.3	311.7	0.5	1.4	3%	8%

Total Deliverable Platelets and Product Volume

	Total Deliverable Platelets (x10^6)		**Product Volume** (mL)	
Donor #	PurePRP® SP	Cervos	PurePRP® SP	Cervos
1	14843	7416	7	4.5
2	9694	4211	7	3.4
3	12105	6184	7.4	4.9
4	13045	5411	7	3.8
5	11451	8382	7.3	3.8
6	10834	5977	6.9	3.5
7	11917	6245	6	3.6
8	11871	6585	7.2	4.3
Average	**11970.0**	**6301.4**	**7.0**	**4.0**
St Dev	1520.4	1249.9	0.4	0.5

WBC Concentration and Recovery

Donor ID	WBC Concentration (x 10^6/mL)		WBC Recovery (%)	
	PurePRP® SP	Cervos	PurePRP® SP	Cervos
1	28.3	3.5	50%	4%
2	9.8	1.3	37%	2%
3	27.1	2.9	54%	4%
4	32	8.1	56%	7%
5	16.9	8.7	23%	6%
6	10.3	4.4	41%	8%
7	16.9	1.6	32%	2%
8	10.5	5.5	28%	9%
Average	**19.0**	**4.5**	**40%**	**5%**
St Dev	9.0	2.8	12%	3%

RBC Concentration and Recovery

Donor ID	RBC Concentration (x 10^9/mL)		RBC Recovery (%)	
	PurePRP® SP	Cervos	PurePRP® SP	Cervos
1	0.2	0.04	0.60%	0.10%
2	0.27	0.11	0.90%	0.20%
3	0.92	0.05	3.50%	0.10%
4	0.8	0.27	2.50%	0.50%
5	0.49	0.12	1.50%	0.20%
6	0.27	0.03	0.80%	0.00%
7	0.45	0.06	1.20%	0.10%
8	0.33	0.07	1.00%	0.10%
Average	**0.5**	**0.1**	**2%**	**0%**
St Dev	0.3	0.1	1%	0.2%

Platelet Activation – PurePRP® SP

Donor ID	(% p-selectin expression)		
	Baseline (Non-Activated)	PRP Non-Activated	PRP ADP-Activated
1	4.6	3.7	97.5
2	4.6	5.5	98.9
3	4.8	3.7	96
4	5.4	4.4	97
5	4	3.8	97.4
6	6.6	10.8	97.7
7	0.4	1.5	97.3
8	0.9	5.1	97.1
Average	**3.9**	**4.8**	**97.4**
St Dev	2.2	2.7	0.8

Platelet Activation – Cervos

Donor ID	(% p-selectin expression)		
	Baseline (Non-Activated)	PRP Non-Activated	PRP ADP-Activated
1	1.5	1.8	98.1
2	2.1	4	98.5
3	3.4	2.7	96.1
4	2.9	2.5	97.7
5	1.8	7.2	97.5
6	3.3	6.9	97.6
7	0.9	1.2	97.5
8	1.6	3.6	97.2
Average	**2.2**	**3.7**	**97.5**
St Dev	0.9	2.2	0.7