



Test Report

Prepared for:
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**Comparison Testing
of**

PurePRP II® 60mL and PURE TWO 60mL Platelet Concentrating Systems

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Study Objective:

The objective of this study was to compare platelet concentrates prepared using Emcyte Corporation's PurePRP® II 60mL and PURE TWO 60mL Platelet Concentrating Systems.

Study Design:

Up to 120 mL of human whole blood was drawn from each of 10 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 than 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 10% Na citrate anticoagulant. 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 Recovery (%)

Cell 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 WBC, RBC 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®II and PURE TWO Platelet Concentrating systems were compared in a paired donor study design. Platelet concentrates were prepared using the Emcyte Sapphire Series centrifuge with the PurePRP® 60 double spin protocol. Both systems utilize two devices, with the first device creating a platelet plasma suspension (PPS) with the majority of red cells removed, following a brief initial spin. The second concentrating device is used for production of the platelet-rich buffy coat and separation of platelet poor plasma (PPP) during the second centrifuge step. The final platelet-rich plasma product is harvested following removal of the majority PPP volume followed by subsequent buffy coat resuspension. While both devices produce platelet-rich concentrates with significantly enriched platelet content, the design of the new device allows for easier handling throughout processing and complete removal of the product during harvesting at the final processing step.

The mean platelet recovery for the PURE TWO system was 90%, with an average total deliverable platelet count of ~12.4 billion. The mean platelet recovery for the PurePRP® II device was 88%, with ~11.8 billion total deliverable platelets. PRP product volumes were 7.2mL for both devices. The platelet concentration factors were similar – 7.3- (PURE TWO) and 7.2- (PurePRP® II) fold increase over baseline concentrations. The PURE TWO concentrate products had significantly greater WBC recovery of 39%, compared to 22% for the PurePRP® II system. There were no significant differences between PurePRP® II and PURE TWO products in red cell content or recovery. For both systems, less than 1% of red blood cells remain 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 (>90%) 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)	Hematocrit (%)
PurePRP® II	9.5 ± 6.6	1645 ± 329	0.1 ± 0.0	1.1 ± 0.3
PURE TWO	16.4 ± 7.0	1728 ± 355	0.2 ± 0.4	2.1 ± 2.7

Summary – Platelet Parameters (Mean ± SD)

Device	PLT Yield (%)	Total Deliverable PLTs (x10 ⁶)	PLT Concentration Factor (x baseline)	Product Volume (mL)
PurePRP® II	88 ± 7	11742 ± 2513	7.2 ± 0.6	7.1 ± 0.2
PURE TWO	90 ± 6	12387 ± 2320	7.3 ± 0.7	7.2 ± 0.4

Summary – Platelet Activation (Mean ± SD)

Device	PLT Activation - Resting (% p selectin expression)	PLT Activation - ADP (% p selectin expression)
PurePRP® II	8.1 ± 5.0	95.3 ± 2.1
PURE TWO	9.3 ± 6.5	94.1 ± 3.7

Baseline Hematology – PURE TWO

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	5.6	4.6	42.8	279
2	4.8	3.9	36.4	186
3	5.0	5.5	42.1	232
4	5.5	4.6	39.9	150
5	4.3	3.8	33.5	245
6	4.7	4.1	31.9	311
7	7.6	3.6	34.6	206
8	5.2	4.4	37.5	249
9	5.7	3.8	35.9	259
10	5.1	4.1	35.6	234
Average	5.3	4.2	37.0	235
St Dev	0.8	0.5	3.4	44

Baseline Hematology - PurePRP® II

Donor ID	WBC (x 10 ⁶ /mL)	RBC (x 10 ⁹ /mL)	Hct (%)	PLT (x 10 ⁶ /mL)
1	5.6	4.6	42.8	279
2	5.0	4.0	36.2	176
3	4.9	5.7	43.7	229
4	5.5	4.6	39.9	150
5	4.3	3.8	33.5	245
6	4.7	3.9	30.7	292
7	7.3	3.5	33.6	190
8	5.0	4.4	38.1	240
9	5.4	3.8	35.9	255
10	5.2	4.2	36.8	236
Average	5.3	4.3	37.1	229
St Dev	0.8	0.6	3.9	42.5

Platelet Concentration, Platelet Concentration Factor and Platelet Recovery

Donor ID	PLT Concentration (x 10 ⁶ /mL)		PLT Concentration Factor (x baseline)		PLT Recovery (%)	
	PurePRP® II	PURE TWO	PurePRP® II	PURE TWO	PurePRP® II	PURE TWO
1	1993	2012	7.1	7.2	89%	93%
2	1205	1164	6.8	6.3	84%	82%
3	1510	1527	6.6	6.6	80%	89%
4	1189	1130	7.9	7.5	96%	96%
5	1534	1945	6.3	7.9	76%	96%
6	2094	2058	7.2	6.6	91%	78%
7	1365	1446	7.2	7.0	87%	85%
8	1574	1982	6.6	8.0	84%	89%
9	2023	2065	7.9	8.0	97%	98%
10	1964	1952	8.3	8.3	97%	97%
Average	1645	1728	7.2	7.3	88%	90%
St Dev	329	355	0.6	0.7	7%	6%

Total Deliverable Platelets and Product Volume

Donor #	Total Deliverable Platelets (x10 ⁶)		Product Volume (mL)	
	PurePRP® II	PURE TWO	PurePRP® II	PURE TWO
1	14350	15093	7.2	7.5
2	8435	8848	7.0	7.6
3	10567	12218	7.0	8.0
4	8323	8363	7.0	7.4
5	10735	13614	7.0	7.0
6	15701	14404	7.5	7.0
7	9554	10119	7.0	7.0
8	11644	12885	7.4	6.5
9	14360	14659	7.1	7.1

Test Report: Emcyte PurePRP® II vs PURE TWO

10	13745	13662	7.0	7.0
Mean	11742	12387	7.1	7.2
St Dev	2513	2320	0.2	0.4

WBC Concentration, RBC Concentration and Hematocrit

Donor ID	WBC Concentration (x 10 ⁶ /mL)		RBC Concentration Factor (x 10 ⁹ /mL)		Hematocrit (%)	
	PurePRP® II	PURE TWO	PurePRP® II	PURE TWO	PurePRP® II	PURE TWO
1	17.6	23.7	0.2	0.1	1.8	1.0
2	1.7	7.5	0.1	0.0	0.8	0.3
3	15.6	19.7	0.1	0.2	1.0	2.0
4	2.5	12.1	0.1	0.1	0.7	0.9
5	2.2	28.2	0.1	0.4	0.8	3.7
6	9.1	16.6	0.2	1.3	1.4	9.7
7	12.6	22.5	0.1	0.1	1.0	1.1
8	4.4	9.0	0.1	0.1	0.9	0.5
9	21.2	17.8	0.1	0.1	1.3	0.8
10	8.3	6.9	0.1	0.1	0.8	1.0
Average	9.5	16.4	0.1	0.2	1.1	2.1
St Dev	6.6	7.0	0.0	0.4	0.3	2.7

WBC and RBC Recoveries

Donor #	WBC Recovery (%)		RBC Recovery (%)	
	PurePRP® II	PURE TWO	PurePRP® II	PURE TWO
1	39%	54%	0.5%	0.2%
2	4%	20%	0.3%	0.1%
3	39%	53%	0.2%	0.5%
4	5%	28%	0.2%	0.2%
5	6%	79%	0.3%	1.3%
6	25%	42%	0.6%	3.6%
7	21%	36%	0.3%	0.3%
8	11%	19%	0.3%	0.1%
9	48%	38%	0.4%	0.2%
10	19%	16%	0.2%	0.3%

Test Report: Emcyte PurePRP® II vs PURE TWO

Mean	22%	39%	0.3%	0.7%
St Dev	15%	19%	0.1%	1.0%

Platelet Activation (% p-selectin expression)

Donor ID	Non-Activated			ADP-Activated	
	Baseline	PurePRP® II	PURE TWO	PurePRP® II	PURE TWO
1	4.5	4.2	5.8	95.3	95.0
2	7.2	15.7	13.3	96.7	96.6
3	5.5	6.3	6.0	91.1	92.0
4	9.2	7.2	7.1	97.2	97.9
5	4.3	9.3	19.9	98.1	98.5
6	10.9	13.7	11.0	96.1	95.8
7	13.0	15.7	21.0	92.4	85.1
8	2.9	3.9	3.2	96.1	95.7
9	3.6	2.9	3.7	96.3	91.3
10	2.7	1.8	2.1	94.0	93.7
Average	6.4	8.1	9.3	95.3	94.1
St Dev	3.4	5.0	6.5	2.1	3.7