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Test Report

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Comparison Testing of Platelet Concentrating Systems:

EmCyte PurePRP-SP vs APEX Biologix XCELL PRP

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1. Objective of Study

The objective of this study was to evaluate platelet parameters associated with the platelet concentrates produced by the EmCyte PurePRP-SP device and the Apex Biologix XCell PRP device.

2. Study Design

This was a single center study conducted by BioSciences Research Associates, Inc. (BSR). BSR provides custom contract research and laboratory services for product development, medical device testing and clinical trials support to Pharmaceutical and Biotechnology companies. All studies are conducted within BSR's Quality Systems and are cGXP compliant. BSR has extensive experience with development and testing of platelet concentration devices and product evaluation, including support for FDA CBER and CDER filings.

Up to ~120 ml of human whole blood was obtained from each of 12 donors following informed consent. The informed consent forms and blood collection protocols were approved by the New England Independent Review Board, Protocol number 04-144 expiration date 06 April 2020. Donors met 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 were no exclusion specifications, other than the donor be healthy. There was no selection for age, sex or ethnicity. Donors are referenced only by assigned code numbers.

Blood was drawn into 60cc syringes preloaded with anticoagulant. For the PurePRP-SP device, whole blood was drawn with 6mL of sodium citrate for a total volume of 60mL of anticoagulated whole blood. For the XCell PRP device, whole blood was drawn with 9mL of ACDA for a total volume of 60mL of anticoagulated whole blood. Platelet concentrates were prepared according to manufacturer's IFU and assessed immediately after processing. Both PurePRP-SP and XCell PRP products were prepared with minimal red blood cell content. Devices were evaluated using paired donor samples.

3. Study Parameters

3.1 Platelet Counts

Complete blood counts were performed using a hematology analyzer for the baseline and platelet concentrate samples. The platelet (PLT) counts were recorded for each sample. Complete blood counts were tested according to SOP: TM-076 Coulter AcT-diff 2 Hematology analyzer.

3.2 Platelet Concentration Factor

Complete blood counts were performed using a hematology analyzer for the baseline and platelet concentrate samples. The platelet concentration factor, which is the ratio of the concentration of platelets in the platelet concentrate product to the concentration of platelets in anticoagulated baseline sample, was determined for each device.

3.3 Platelet Recovery

Complete blood counts were performed using a hematology analyzer for the baseline and platelet concentrate samples. The platelet recovery, which is the ratio of the concentration of platelets in the platelet concentrate product to the concentration of platelets in anticoagulated baseline sample, was determined for each device.

3.4 Platelet Derived Growth Factor (PDGF)

Growth factor analysis was performed on releasates prepared from baseline samples and platelet concentrates. PDGF concentration for each sample was determined by quantitative ELISA.

Table 1. Platelets x 10^6/mL: **Baseline**

Sample ID	Emcyte	Apex
3102	179	156
3103	191	151
3104	204	166
3105	270	222
3106	305	271
3107	338	319
3108	235	217
3109	237	225
3110	153	135
3111	216	233
3112	214	201
3113	155	141
Mean	**225**	**203**
St Dev	54.3	53.8

Table 2. Platelets x 10^6/mL – **Products**

Sample ID	**Emcyte**	**Apex**
3102	1176	900
3103	1272	1114
3104	1448	998
3105	1792	1008
3106	1972	1452
3107	2151	1359
3108	1428	900
3109	1522	1496
3110	839	607
3111	1246	1086
3112	1496	989
3113	1270	999
Mean	**1468**	**1076**
St Dev	346	242

Table 3. Platelet Recovery (%), Platelet Concentration Factor (x baseline), Product Volume (mL)

	PLT Recovery		PLT Concentration Factor		Product Volume	
Donor ID	**EmCyte**	**Apex**	**EmCyte**	**Apex**	**EmCyte**	**Apex**
3102	76%	53%	6.6	5.8	6.7	5.4
3103	84%	73%	6.7	7.4	7.3	5.8
3104	81%	57%	7.1	6.0	6.4	5.3
3105	79%	50%	6.6	4.5	6.7	5.9
3106	79%	54%	6.5	5.4	6.8	5.5
3107	83%	45%	6.4	4.3	7.3	5.8
3108	80%	45%	6.1	4.1	7.1	6.0
3109	88%	69%	6.4	6.6	7.5	5.8
3110	80%	46%	5.5	4.5	8.0	5.6
3111	84%	49%	5.8	4.7	8.0	5.8
3112	97%	48%	7.0	4.9	7.8	5.4
3113	95%	68%	8.2	7.1	6.4	5.3
Mean	**84%**	**55%**	**6.6**	**5.4**	**7.2**	**5.6**
St Dev	6	9	0.7	1.1	0.6	0.2

Table 4: Total Deliverable Platelets x 10^6/mL

			Product Volume	
Donor ID	EmCyte	Apex	**EmCyte**	**Apex**
3102	7,879	4,860	6.7	5.4
3103	9,286	6,461	7.3	5.8
3104	9,267	5,289	6.4	5.3
3105	12,006	5,947	6.7	5.9
3106	13,410	7,986	6.8	5.5
3107	15,702	7,882	7.3	5.8
3108	10,139	5,400	7.1	6.0
3109	11,415	8,677	7.5	5.8
3110	6,712	3,399	8.0	5.6
3111	9,968	6,299	8.0	5.8
3112	11,669	5,341	7.8	5.4
3113	8,128	5,295	6.4	5.3
Mean	**10,465**	**6,070**	**7.2**	**5.6**
St Dev	2,419	1,436	0.6	0.2

Table 5: PDGF Concentration (pg/mL)

Donor ID	Baseline	Emcyte	Baseline	Apex
3102	11,460	39,270	10,379	11,157
3103	7,970	35,795	7,537	13,642
3104	8,559	51,346	8,888	11,978
3105	11,116	60,377	11,348	10,741
3106	8,935	39,890	9,478	11,847
3107	20,973	82,802	19,642	18,021
3108	10,422	45,922	11,625	13,035
3109	14,417	54,699	10,382	17,703
3110	12,057	40,820	12,366	10,654
3111	11,696	33,968	11,788	15,098
3112	12,517	54,445	14,283	16,346
3113	9,632	58,916	11,028	6,745
Mean	**11,646**	**49,854**	**11,562**	**13,081**
St Dev	3315	13177	2947	3146

Summary

This study compared two platelet concentrating systems that utilize conventional centrifuges with swing bucket rotors and that are processed via two-spin protocols. Both the EmCyte PurePRP® SP and Apex XCell PRP are loaded via syringe through ports located at the top of the device. The EmCyte system is a completely closed system, equipped with self-sealing ports for loading and retrieval of product, while the Apex system is an open system, which leaves a greater chance for product contamination during processing. In addition to the increased risk of contamination due to the open nature of the Apex system, there is also an increased risk of spillage during handling and processing.

The goal of this study was to evaluate the PRP products produced with two platelet concentrating systems – EmCyte PurePRP® SP and Apex XCell PRP. The mean platelet concentration factor for the EmCyte product was 6.6-fold higher than baseline in an average volume of 7.2mL. For the Apex product, the mean platelet concentration factor was 5.4-fold higher than baseline in an average volume of 5.6mL. The EmCyte product had significantly better platelet yields, with an average yield of 84%, compared to the Apex products which had an average recovery of 55%. The mean platelet deliverable for the EmCyte product was 10,465 and was ~30% greater compared to the Apex platelet deliverable of 6,070. The growth factor (PDGF) concentrations of the EmCyte products were also substantially higher with an average PDGF concentration that was 3.8 times higher than the Apex product concentration.

Chart 1: Platelet rich plasma platelet recovery (%)

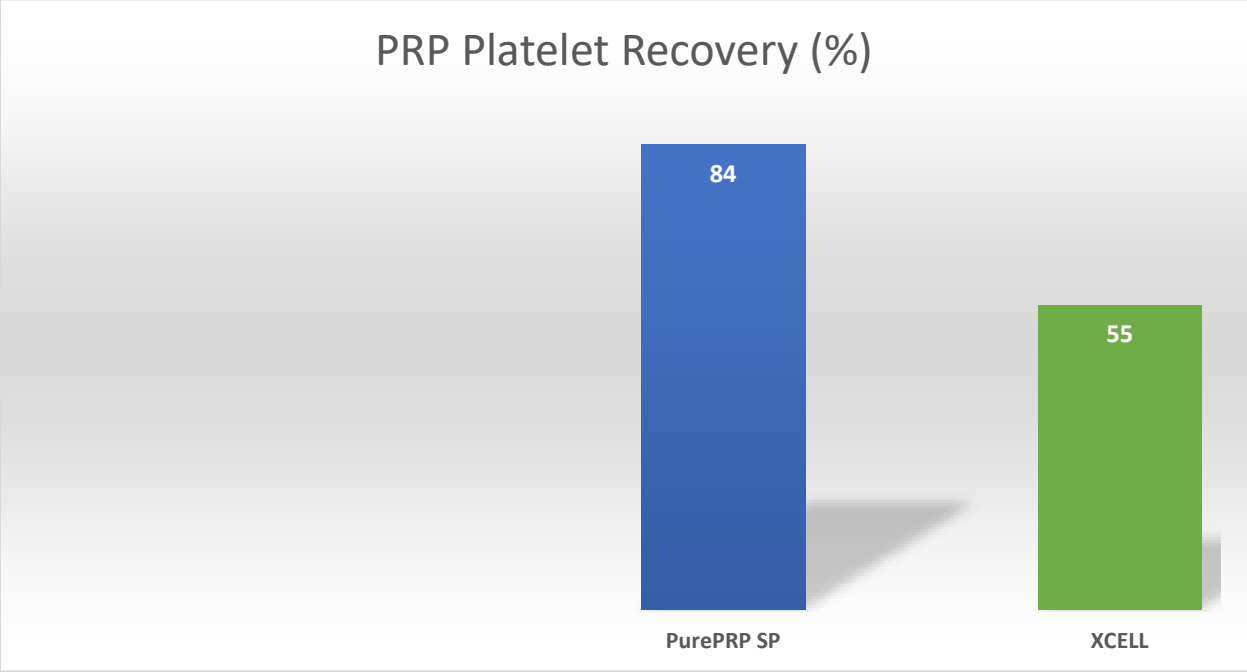

Chart 2: Platelet rich plasma concentration factor over baseline and volume

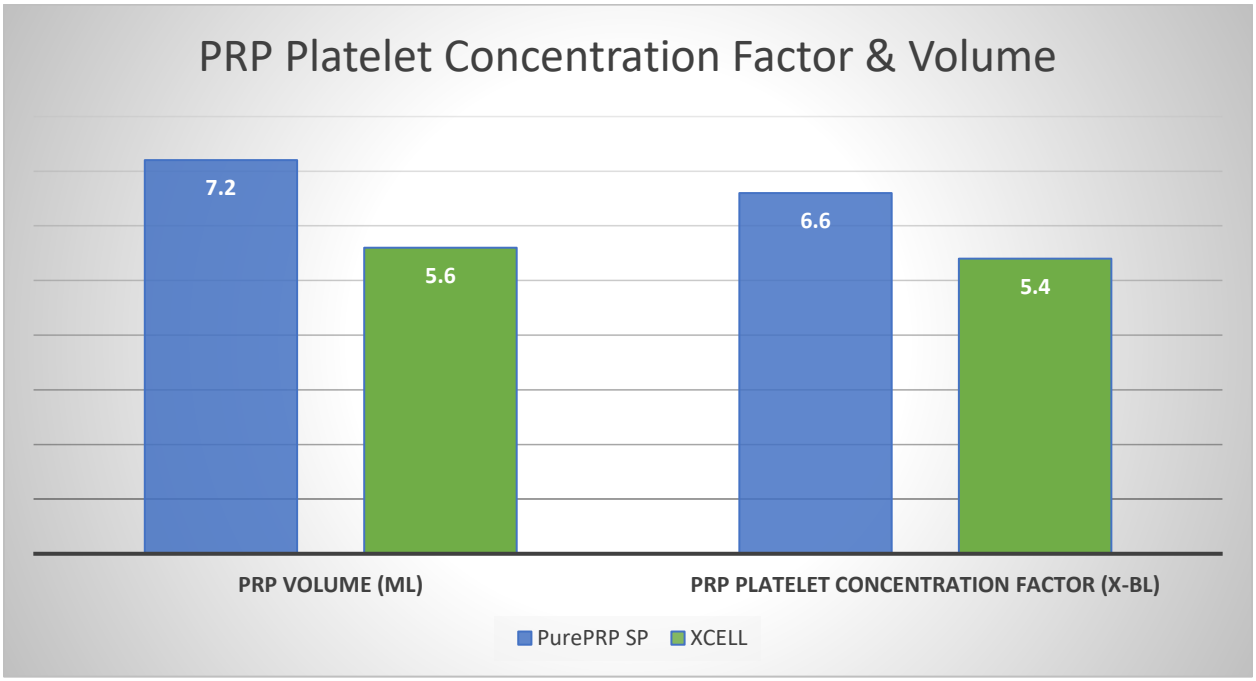

Chart 3: Platelet rich plasma platelet count per mL

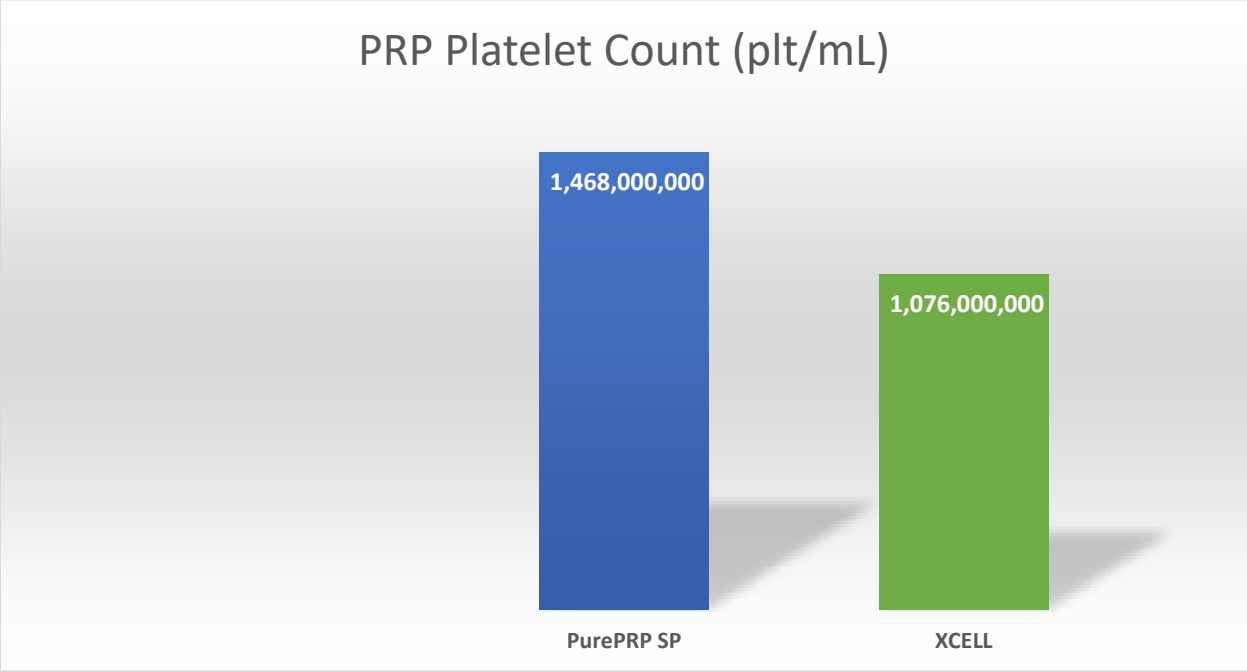

Chart 4: Platelet rich plasma total deliverable platelet content

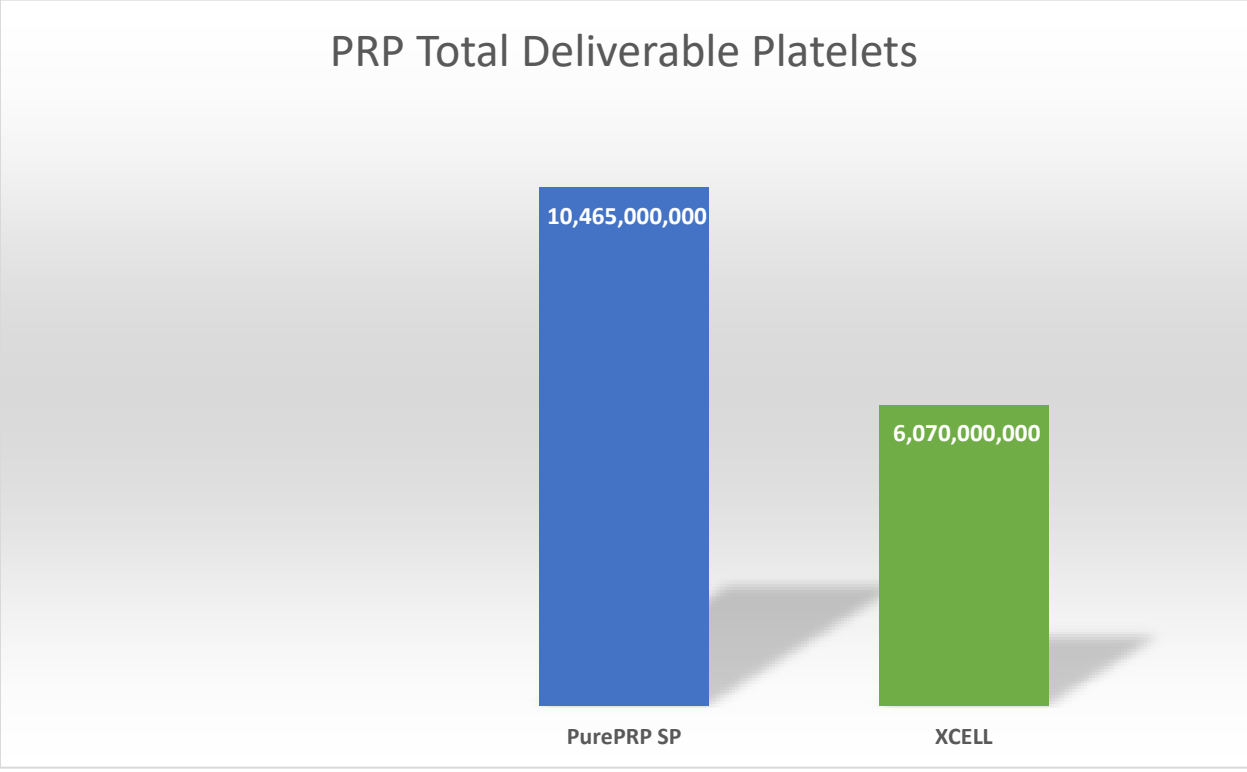

Chart 5: Platelet rich plasma PDGF concentration compared to baseline