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Test Report

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Testing of Platelet Concentrating Systems:

PurePRP® SupraPhysiologic Concentrating System

SPONSOR

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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.

2. Study Design

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. Platelet concentrates were prepared according to manufacturer's IFU and assessed immediately after processing. The PurePRP® SP product was prepared with minimal red blood cell content.

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**
3102	179
3103	191
3104	204
3105	270
3106	305
3107	338
3108	235
3109	237
3110	153
3111	216
3112	214
3113	155
Mean	**225**
St Dev	54.3

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

Sample ID	**Emcyte**
3102	1176
3103	1272
3104	1448
3105	1792
3106	1972
3107	2151
3108	1428
3109	1522
3110	839
3111	1246
3112	1496
3113	1270
Mean	**1468**
St Dev	346

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

Donor ID	Recovery	Concentration	PRP Volume
3102	76%	6.6	6.7
3103	84%	6.7	7.3
3104	81%	7.1	6.4
3105	79%	6.6	6.7
3106	79%	6.5	6.8
3107	83%	6.4	7.3
3108	80%	6.1	7.1
3109	88%	6.4	7.5
3110	80%	5.5	8.0
3111	84%	5.8	8.0
3112	97%	7.0	7.8
3113	95%	8.2	6.4
Mean	**84%**	**6.6**	**7.2**
St Dev	6	0.7	0.6

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

Donor ID	**Deliverable x 10^6/mL**	Product Volume
3102	7,879	6.7
3103	9,286	7.3
3104	9,267	6.4
3105	12,006	6.7
3106	13,410	6.8
3107	15,702	7.3
3108	10,139	7.1
3109	11,415	7.5
3110	6,712	8.0
3111	9,968	8.0
3112	11,669	7.8
3113	8,128	6.4
Mean	**10,465**	**7.2**
St Dev	2,419	0.6

Summary

This platelet concentrating system utilize a conventional centrifuge with swing bucket rotors and was processed according to its respective protocols. The EmCyte PurePRP® SP was 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.

The goal of this study was to evaluate the PRP products produced with the platelet concentrating system EmCyte PurePRP® SP. The mean platelet concentration factor for the EmCyte product was 6.6-fold higher than baseline in an average volume of 7.2mL. The EmCyte product had significantly better platelet yields than what is typically found in a point of care platelet concentrating system, with an average yield of 84%. The mean platelet deliverable for the EmCyte product was 10,465 x 10^6/mL, which is also substantially higher than typical performing systems.

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