BioSciences Research Associates, Inc.
BSR ASSOCIATES, INC.
Contract Biomedical Research & Development

Phone: 617-441-2050
Fax: 617-441-2052
767C Concord Avenue
Cambridge, MA 02138
www.BSRLabs.com

Project 1719 Report

Title: **Performance evaluation of GENESIS BIOLOGICS 15 and 30mL PRP tubes**	
Principal Investigator(s): Dr. Robert Mandle, BioSciences Research Associates, Cambridge, MA Dr. Natalie Stephens, BioSciences Research Associates, Cambridge, MA	
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Revision if applicable (A-Z): New	Revision Date: 05 Sept 2017

Type of Study: Performance Assessment

Objective of Study: Evaluate the performances of GENESIS BIOLOGICS Platelet Rich Plasma (PRP) tubes.

Introduction:
The performances of the GENESIS BIOLOGICS PRP 15 and 30mL tubes were evaluated. Testing was performed to assess blood fill volume, gel performance, PRP volume, platelet concentration and platelet yield.

Experimental design:
For each of fourteen (14) donors,15mL and 30mL tubes were drawn. An EDTA tube was also drawn for baseline measurements.
Four centrifuge speeds were used: 1) 4500g, 10 min; 2) 1020g, 5 – 6 min; 3) 1020g, 10min; 4) 1600g, 10min.

A Drucker centrifuge, Model # 755VES with a swing bucket rotor was used. The centrifuge parameters were as shown in Table I.

Table I**: Centrifuge settings**

Nominal force (xg)	Time (min)
450	10
1020	5 – 6,
1020	10
1200	10
1600	10

Tubes from each donor were processed to produce a PRP concentrate by removing Platelet Poor Plasma (PPP) prior to resuspending platelets. The goal was to produce a reduced volume PRP with a higher platelet concentration factor. For 15mL tubes, all but ~4 mL of the plasma phase was removed prior to PRP harvest. For 30mL tubes all but ~4mL of the plasma phase was removed prior to PRP harvest.
Tubes were inverted 7x according to manufacturer's instructions to resuspend platelets prior to PRP harvest.

Reported parameters:

Percent Platelet recovery: calculated from CBC data, using K_2EDTA tube from each subject as baseline; adjusted for dilution with anticoagulant.

Concentration factor: calculated from CBC data, using K_2EDTA tube from each subject as baseline and adjusted for dilution with anticoagulant. Values reported are for 4.0mL volumes, for 15 and 30mL tubes, respectively.

Draw volume: calculated from weight and blood hematocrit. 15mL tubes were filled by vacuum. 30mL tubes were opened and filled with ~30mL of blood.

Product volume: measured in graduated pipets.

Gel performance: visual inspection, note if gel formed and was positioned at the plasma interface

Results:

Table II**: Fill volume, Product volume, Hemolysis and Gel performance**.

Tube Type	Fill Volume	Product Volume	Gel performance
15mL	12.3 (0.95)	3.4 (0.43)	Good; red cells in suspension were observed in one tube
30mL	32.8 (0.46)	5.8 (2.16)	Good

Mean (Standard deviation); n = 14

Table III**: Mean Platelet Recoveries and Concentration Factor at t = 0 and t = 1hr**

For both 15mL and 30mL tubes, platelet recovery and concentration factor was 2.5 – 2.8-fold immediately after PRP harvest.

To determine whether platelets were trapped in the gel, tubes were rocked gently for a minimum of 1hr to allow platelet release, then platelet counts were repeated.

	PRP (%)		Conc. Factor (x baseline)	
	15mL	**30mL**	**15mL**	**30mL**
0hr	40% (11)	35% (8)	2.5 (0.7)	3.5 (0.7)
1hr	44% (16)	36% (16)	2.8 (1.1)	3.5 (1.4)

Mean (Standard deviation)

Platelet recovery and concentration factor increased for both tubes after 1 hr.

Table IV**: Effect of Speed on Platelet Recovery (%) and Concentration Factor in 15mL Tubes, t = 0**

Several centrifuge speeds (450g – 1600g) were tested to minimize loss of platelets in the plasma fraction.

	% Platelet Recovery		Conc. Factor
	PRP	**PPP**	
450g	35%	45%	2.2
1020g	43%	23%	2.5
1200g	37%	13%	2.7
1600g	24%	3%	2.4

Table V**: Effect of Speed on Platelet Recovery (%) and Concentration Factor in 30mL Tubes, t = 0**

	% Platelet Recovery		Conc. Factor
	PRP	**PPP**	
450g	35%	45%	3.2
1020g	43%	23%	3.5
1200g	37%	13%	3.7
1600g	24%	3%	3.4

While, platelet loss in the plasma fraction was minimal at 1600g, platelet recovery in the PRP concentrate was also lowest at this speed. The highest platelet recoveries were measured at lower speeds.

At all speeds tested, average platelet recoveries were >60% for 15mL and 30mL tubes.

Table VI**: Platelet Recovery (%) in PRP and PPP fractions and Concentration Factor By Donor in 15mL Tubes, t = 0**

	PRP (%)	PPP (%)	Total Yield (%)	Conc. Factor (x baseline)
D1001	32%	60%	92%	3.6
D1002	44%	39%	83%	2.1
D1003	41%	31%	72%	2.2
D1004	36%	21%	57%	3.1
D1005	50%	31%	81%	2.7
D1006	52%	35%	87%	3.6
D1007	44%	4%	48%	2.7
D1008	47%	26%	73%	3.7
D1009	42%	17%	59%	3.4

Table VII**: Platelet Recovery (%) and Concentration Factor By Donor in 30mL Tubes, t = 0**

	PRP (%)	PPP (%)	Total Yield (%)	Conc. Factor (x baseline)
D1002	52%	31%	76%	3.6
D1008	37%	15%	48%	4.1
D1010	45%	12%	52%	3.6
D1013	41%	18%	54%	3.7
D1014	38%	14%	47%	3.4

Discussion:

The gel separator moved and reformed at the plasma interface in all tubes at all centrifuge speeds (450g – 1600g). The average fill volume and product volume were 12.3mL and 2.4mL respectively, in the 15mL tube. The average product volume was 5.8 mL in the 30mL tube. Since the 30mL tubes were opened and the vacuum disrupted to fill each tube, the fill volume of 32.8mL may not be representative of a vacuum-driven draw volume.

The average platelet recoveries were > 60% for the 15mL tube and 30mL tube immediately following PRP harvest for all centrifuge speeds tested.

At 1600g, platelet loss in the PPP was minimal, however PRP yields were also the lowest.

Platelet concentration factor was increased by removal of ~80% of the plasma phase to 2.5-fold (15mL) and 2.8-fold (30mL). An hour of gentle rocking resulted in a minimal increase in platelet recovery of <5% for both tubes, and increased concentration factors to 2.8-fold (15mL) and 3.2-fold (30mL.