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Test Report

Equivalence Testing:
Ranfac Autologous Platelet Separator vs. Predicate Device

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1. Introduction

The objective of this study was to test parameters associated with the platelet concentrates (PC) produced by the Ranfac Platelet Separator device (Test) and the platelet concentrates produced by the Arteriocyte Magellan Autologous Concentration system (Predicate). This study was conducted to support a premarket notification for the Ranfac Platelet Separator devices.

2. Study Design

This is 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 will be obtained from each of 60 donors following informed consent. The consent form and blood collection protocols are approved by the New England Independent Review Board, Protocol number 04-144 expiration date 06 April 2020. 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 specifications, other that the donor be healthy. There will be no selection for age, sex or ethnicity. Donors will be referenced only by assigned code numbers.

Peripheral whole blood was drawn into syringes for production of platelet concentrates. Syringes were also drawn for baseline comparison. Briefly, for the Ranfac system, a total of 60mL of ACDA-anticoagulated whole blood was loaded into two 30mL devices. Blood was processed using a two-spin protocol: Spin 1 – 3200rpm (1600 rcf), 2 min; Spin 2 – 3200 rpm (1600rcf), 6 min. Processing was performed according to manufacturer's instructions for use (Appendix II). For the Arteriocyte system, 60mL of ACDA anticoagulated whole blood was loaded into the Magellan processing system. The 'Standard' program was selected and processing was carried out according to manufacturer's instructions for use. Each platelet concentrate product was analyzed at 0 hour (immediately following processing) and a second product aliquot was analyzed at 4 hours post-processing. Four hours is a realistic worst-case time period that the platelet rich fraction might be held following processing and prior to use in a surgical procedure. The platelet concentrate samples were processed in a non-controlled environment simulating the worst case of the patient point of care. Donor samples were disposed of in biohazardous waste following testing.

3. Study Parameters

The analysis of the parameters outlined below was used to determine substantial equivalence of platelet concentrate obtained from the Test device relative to the platelet concentrate produced with the Predicate device using a paired donor sample design. The analysis compared the Test product against the Predicate product.

3.1. *Platelet Concentration Factor*

Complete blood counts (CBCs) were performed using a 3-part differential hematology analyzer to quantify the platelets contained within the baseline sample, the Test platelet concentrate and the Predicate platelet concentrate (0 and 4 hr). 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. Complete blood counts (CBCs) were tested according to SOP: TM-076 Coulter Ac-T diff 2 Hematology Analyzer.

3.2. *Platelet Yield*

Complete blood counts (CBCs) were performed using a hematology analyzer to quantify the platelets contained within the baseline sample, the Test platelet concentrate and the Predicate platelet concentrate (0 and 4 hr). The platelet yield, which is the ratio of the number of platelets in the platelet concentrate product to the number of platelets in the anticoagulated start sample, was determined for each device. The lower bound of the 95% confidence interval for mean platelet recovery should be at least 50%.

3.3. *pH*

Sample pH was measured in the Test platelet concentrate and the Predicate platelet concentrate (0 and 4 hr). The minimal acceptable pH is 6.2. Testing was conducted according to SOP: TM-128 Blood pH.

3.4. *Platelet Activation*

Measurement of platelet surface p-selectin glycoprotein by flow cytometry to assess the degree of process-dependent platelet activation was performed with the baseline sample, the Test platelet concentrate and the Predicate platelet concentrate (0 and 4 hr). Samples were also analyzed for p-selectin following the addition of adenosine diphosphate (ADP) agonist to evaluate platelet function. The testing method was conducted according to SOP: TM-003: Cytometric Analysis of the P-Selectin.

3.5. *Platelet Aggregation*

Platelet ability to aggregate in response to collagen agonist was measured in the Test platelet concentrate and the Predicate platelet concentrate (0 and 4 hr). Aggregation was assessed using an optical aggregometer. The testing method was conducted according to SOP: TM-089 Optical Platelet Aggregation with Collagen Agonist.

3.6. *Hypotonic Stress Response*

The ability of platelets to recover shape and volume following a hypotonic exposure was evaluated for the Test platelet concentrate and the Predicate platelet concentrate (0 and 4 hr). Hypotonic Stress Response was measured by monitoring changes in light transmission after platelet sample exposure to dilution by water. The testing method was conducted according to SOP: TM-016 Hypotonic Stress Response.

3.7. *White Blood Cell, Red Blood Cell and Platelet Counts*

Complete blood counts (CBCs) were performed using a hematology analyzer for the

baseline sample, the Test platelet concentrate and the Predicate platelet concentrate (0 and 4 hr). The White Blood Cell (WBC), Red Blood Cell (RBC) and Platelet counts were recorded for each sample. Complete blood counts (CBCs) were tested according to SOP: TM-076 Coulter Ac-T diff 2 Hematology Analyzer.

3.8. *Bone Graft Retention*

The stability of the clot formed when platelet concentrate is mixed with calcium chloride and clotted around granular demineralized bone was determined for 12 donors. The response of this composite clot to mechanical stress was determined for Test and Predicate platelet concentrates at 4 hrs post-processing, the worst case for this indication specific assay as both platelet function and coagulation protein function can be expected to degrade with time. The percent of the initial graft material remaining in the largest composite clot after being subjected to mechanical stress is reported. Testing was carried out according to SOP: BSR-TM037.

4. Sample Size

The sample size is based on consultation with the U.S. FDA Center for Biologics Evaluation and Research (CBER) and is consistent with the sample sizes required for similar device equivalence testing. Samples for analysis were based on project schedule without donor selection. The table below shows parameters evaluated, timepoints and number of donors for each analysis.

Test	Blood	Test t=0	Test t=4	Predicate t=0	Predicate t=4
WBC, RBC, Platelet count	60	60	60	60	60
Platelet yield	-	60	60	60	60
Platelet concentration factor (x baseline)	-	60	60	60	60
pH	-	26	26	26	26
p-Selectin (resting, ADP-activated)	12	12	12	12	12
Platelet aggregation	-	12	12	12	12
Hypotonic stress response (HSR)	-	12	12	12	12
Bone Graft Retention	-	-	12	-	12

Test Devices:

- Ranfac Autologous Platelet Separator, Catalog # 76101-01M; Lot # 43507

Predicate Device:

- Arteriocyte Magellan Autogolous Concentration System, Catalog # AMS300; Lot 19070210

Centrifuge:

- Eppendorf, Model 5702

5. Analysis Populations

5.1. Intent-to-Process

The intent-to-Process population is defined as all donor blood samples except samples with an inadequate volume and samples that are clotted or otherwise unfit for processing. It was anticipated that a replacement donor would be recruited if a blood sample was deemed unfit for processing.

5.2. Per-Protocol

There were no specific exclusions other than that the donor be healthy and normal. The Per-Protocol population was equivalent to the Intent-to-Process population.

6. Data and Analysis

6.1 Derived and transformed variables

Derived and transformed variables were created as needed for study analyses and are discussed in the section describing the analysis of study parameters.

6.2 Missing values

No attempts were made to impute missing values.

6.3 Interim Analysis

There was no interim analyses.

6.4 Software

Microsoft EXCEL 2016 Version 16.0.8625.2121 was used for analysis.

7. Statistical Methods

Data tables and descriptive statistics are shown for each parameter for both Test and Predicate devices. A determination of equivalence was based on the level of similarity between the products of the test and predicate systems in a paired design. The mean and standard deviation of log transformed, paired sample ratios (Test/Predicate) were estimated and used to construct the two-sided 90% confidence intervals (one-sided 95% for Platelet Yield). For parameters evaluated, it is reported whether the lower confidence bound (LCB) excludes values representing 80% of the predicate mean and the upper bound excludes 125%. The confidence interval was calculated as follows:

$$\text{Confidence intervale} = \mu \pm z_{90}\sqrt{\frac{\sigma^2}{N}}$$

Where means and standard deviations are estimates of ln (T/P) distribution and N is the number of observations.

7.1 *Platelet Concentration Factor*

The platelet concentration factor (PCF) was derived as the ratio of the platelet count in the platelet concentrate (PCPRP) to the platelet count in baseline sample (PCWB):

PCF = PCPRP/PCWB

Results are summarized in tables showing the number of observations, mean platelet count and standard deviation; mean platelet concentration factor and standard deviation for each device at times 0 and 4hr.

7.2 *Platelet Yield*

The platelet yield (PY) was derived as the ratio of the platelet count in the platelet concentrate (PCPRP) times the volume of the platelet concentrate (VPRP) to the platelet count in the baseline sample (PCWB) times the volume of the sample processed (VWB):

PY = (PCPRP*VPRP)/(PCWB*VWB)

Results are summarized in tables showing the number of observations, mean platelet yield and standard deviation for each device at times 0 and 4hr. The minimum acceptable average platelet yield for the Test device is 50%.

7.3 *pH*

The means and standard deviations for sample pH measured for each device (0 and 4 hr) are presented. The pH of the Test platelet concentrate must be greater than a pH of 6.2.

7.4 *Platelet Activation*

Platelet process-dependent activation and platelet response to ADP agonist are reported as percent of activated platelets[1]. Resting platelets in ACD-A anticoagulated whole blood typically have less than 13% activated platelets. ADP stimulated whole blood typically results in greater than 70% activated platelets. Results are summarized in tables showing the donor number, percent of activated platelets, both resting and stimulated, for each device at times 0 and 4hr.

7.5 *Platelet Aggregation*

Platelet aggregation in response to collagen agonist are reported as Normal or Abnormal. A normal platelet response to collagen includes: a) an aggregation response that is at least 60% of maximum aggregation (defined by donor's platelet poor plasma), and b) a lag phase often with a noticeable decrease in light transmission before the aggregation phase begins [2,3,4]. Results are summarized in tables showing the donor number, percent aggregation and lag phase length for each device at times 0 and 4hr.

7.6 *Hypotonic Stress Response*

Platelet response to osmotic challenge are reported as percent reversal (R)[5,6]:

R= 100(Tm-T)/(Tm-Tb)

Where Tm =maximum reading after addition of water; T= reading at 10 min; and Tb = baseline.
Damaged platelets will not recover after osmotic challenge. Results are summarized in tables showing the donor number and percent reversal for each device at times 0 and 4hr.

7.7 *Nucleated Cells, Erythrocytes and Platelet Counts*

Nucleated Cells (NC), Erythrocyte (RBC) and Platelet values are summarized in tables for baseline samples and each device concentrate samples (0 and 4 hr).

7.8 *Bone Graft Retention*

Bone graft retention results are reported as the percent of starting weight of graft material remaining in the largest intact piece of the composite clot after mechanical testing. Results are summarized in tables showing the donor number, percent of graft composite retained for each device and ratio of clot retained compared to saline control.

8. Adverse, Serious Adverse Events

There were no adverse, or serious adverse events.

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10. Conclusions

A finding of equivalence between the platelet concentrates produced by the Ranfac Platelet Separator Device **(Test)** and the Arteriocyte Magellan Autologous Concentration system **(Predicate)** is supported by the data from this study. The mean Platelet Yields for the Test device were substantial with 78% recovery at time 0hr and 77% recovery at time 4hr. The mean Platelet recoveries for the Predicate device were 68% at both timepoints. The platelet recoveries exceeded the minimum acceptable average platelet yield of 50%.

The Ranfac device produced an average platelet concentration in PRP that was on average 6 times the baseline platelet concentration for 0hr and 4hr samples. The average Platelet concentration factor for the Predicate product was 5.6 times baseline at 0hr and 4hrs. The mean pH of the Test product was 6.8 and 6.9 for 0hr and 4hr samples and for the Predicate PRP and the mean pH was 7.2 for both time intervals, thereby meeting the specification for a pH value > 6.2.

The mean p-selectin expression on resting platelets of the Ranfac concentrates was 5% in 0hr samples and 6.4% 4hrs post-processing. Predicate concentrates had a mean p-selectin expression of 5.4% (0hr) and 7.7% (4hr). There was no evidence of significant device-dependent platelet activation. A robust platelet response to ADP-stimulation was measured in both Test and Predicate products, with 97% p-selectin expression at 0hr and at 4hrs.

Platelet function was normal as assessed by platelet aggregation and hypotonic stress response. The mean platelet aggregation was 69% at 0hr and 70% at 4hr for the Test product. The Predicate products had an average platelet aggregation of 73% at both timepoints. The mean hypotonic stress response at 0hrs was ~ 80% reversal for Test and Predicate platelet concentrates. At 4hrs, the hypotonic stress response was 71% for the Test concentrate and 65% for the Predicate concentrate. The retention of bone graft material was excellent, with >80% graft material recovery for both PRP products, and was ~7 times greater when compared to the saline control.

11. References

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5. Farrugia A, Hughes C, Douglas S, Neal M, and James J. Microtiter plate measurement of platelet response to hypotonic stress. J. Clin Path. 1989; 42:1298-1301.

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APPENDIX I: List of Standard Operating Procedures to be used in the study

SOP Code	SOP Title
TM-003	Cytometric Analysis of the P-Selectin
TM-016	Hypotonic stress response
TM-037	Bone Graft Retention
TM-076	Coulter Ac-T diff 2 Hematology Analyzer
TM-089	Optical Platelet Aggregation with Collagen Agonist
TM-128	Blood pH

Table 9.1: Subject and Sample Disposition

Total number of donors Used in this Study	**62**
Discarded Samples Samples clotted in syringes prior to processing	2

Table 9.2: Hematology Data – Baseline
WBC – White Blood Cells; RBC – Red Blood Cells; Hct – Hematocrit; PLT – Platelets

Sample ID	WBC x 10^6/mL	RBC x 10^9/mL	Hct (%)	PLT x 10^6/mL
1	6.4	4.35	40.6	168
2	4.1	4.55	37.3	187
3	8.7	4.11	36.0	200
4	5.9	5.06	46.2	270
5	4.9	3.54	33.5	202
6	8.4	4.87	34.6	242
7	6.3	4.54	38.2	123
8	3.8	4.27	41.3	203
9	6.6	4.84	42.4	204
10	4.2	4.23	33.9	293
11	9.8	3.58	34.4	249
12	7.5	4.64	39.4	106
13	4.3	4.70	36.0	193
14	5.0	3.59	33.2	149
15	5.1	3.67	30.8	192
16	7.0	4.72	37.8	189
17	7.1	3.67	38.8	149
18	6.2	3.27	31.2	287
19	5.5	4.31	35.6	304
20	5.1	3.65	34.0	313
21	3.0	3.07	31.6	105
22	4.4	3.16	28.5	111
23	6.2	4.54	42.2	213
24	7.9	4.35	38.7	175
25	4.2	4.42	35.7	338
26	5.1	4.10	39.7	160
27	5.0	3.53	31.7	223
28	3.6	4.72	39.7	128
29	8.7	3.80	38.8	168
30	6.0	3.80	33.5	247
31	8.1	3.71	35.8	267
32	4.8	4.07	36.6	143
33	6.3	4.09	38.3	200
34	6.1	4.29	36.7	191
35	6.2	4.41	32.6	257
36	3.0	3.85	34.5	213
37	6.5	4.35	42.3	218

Sample ID	WBC x 10^6/mL	RBC x 10^9/mL	Hct (%)	PLT x 10^6/mL
38	5.2	4.40	39.2	222
39	5.3	4.53	33.9	118
40	4.8	3.87	34.8	166
41	4.8	4.16	32.5	266
42	5.7	4.20	36.6	165
43	4.2	4.70	38.8	221
44	6.6	4.18	35.2	118
45	7.1	3.78	31.1	229
46	5.3	3.81	37.3	271
47	4.7	4.67	42.4	146
48	3.9	3.81	35.8	191
49	3.7	4.41	39.9	210
50	3.8	3.46	35.2	256
51	8.1	4.09	36.8	288
52	6.1	4.30	39.6	162
53	5.0	5.18	43.7	185
54	4.7	4.64	42.6	304
55	11.6	4.89	42.5	204
56	5.4	3.99	35.2	179
57	4.8	4.63	39.1	213
58	8.5	3.90	35.7	258
59	5.6	4.25	33.6	184
60	5.3	3.66	33.7	193
Mean	**5.8**	**4.2**	**36.8**	**205**
St Dev	1.7	0.5	3.7	56

Table 9.3: White Blood Cell Concentration (WBC x 10^6/mL)**, 0hr**

Sample ID	Test	Predicate
1	16.5	20.0
2	9.8	6.8
3	12.6	15.6
4	7.0	20.0
5	17.2	23.0
6	10.3	23.4
7	9.3	16.4
8	8.4	12.4
9	15.8	22.4
10	6.2	8.2
11	15.2	22.0
12	10.7	29.4
13	5.3	9.4
14	10.5	15.9
15	8.1	10.3
16	11.0	25.2
17	7.0	21.3
18	14.6	18.4
19	8.4	13.4
20	24.0	29.4
21	10.2	36.6
22	4.1	5.4
23	20.4	21.6
24	16.6	20.0
25	8.4	15.0
26	9.7	13.4
27	7.6	7.6
28	9.8	11.3
29	21.7	41.5
30	11.6	18.0
31	18.0	27.8
32	11.6	13.9
33	12.6	17.8
34	8.2	15.5
35	8.2	17.6
36	7.4	11.0
37	13.0	16.2
38	13.6	16.6

Sample ID	Test	Predicate
39	6.2	12.2
40	6.8	15.4
41	7.0	12.4
42	5.4	20.4
43	7.2	12.8
44	11.8	19.6
45	14.0	16.0
46	14.2	18.0
47	9.9	10.5
48	11.0	9.5
49	9.4	10.0
50	8.8	11.4
51	15.0	27.8
52	12.4	31.4
53	10.4	13.1
54	16.6	20.0
55	19.2	19.7
56	16.2	23.9
57	13.8	15.6
58	10.4	20.0
59	7.8	13.6
60	13.6	20.8
Mean	**11.5**	**17.7**
St Dev	4.3	7.1

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.69	-0.43	0.65	**0.61 – 0.70**
St Dev	0.21	0.33		

With respect to WBC concentration at t=0hr, the 90% confidence interval does not exclude values < 0.80.

Table 9.4: White Blood Cell Concentration (WBC x 10^6/mL)**, 4hr**

Sample ID	Test	Predicate
1	16.7	20.6
2	9.4	7.2
3	12.6	15.6
4	6.8	20.6
5	18.0	24.4
6	9.4	23.1
7	9.0	16.5
8	8.2	12.6
9	16.4	22.2
10	6.4	8.2
11	15.4	22.4
12	10.3	27.4
13	5.1	9.2
14	10.2	15.1
15	8.4	10.7
16	10.6	24.8
17	7.1	21.3
18	14.4	17.2
19	8.2	12.0
20	22.8	27.4
21	10.0	34.4
22	4.0	5.6
23	20.4	22.4
24	16.8	20.2
25	8.4	14.7
26	9.6	13.8
27	7.4	7.4
28	9.5	11.2
29	21.5	41.3
30	11.2	18.0
31	18.0	27.4
32	11.4	12.9
33	12.2	18.0
34	7.4	14.7
35	7.4	17.0
36	7.4	10.8
37	11.8	15.8
38	14.8	16.8

Sample ID	Test	Predicate
39	5.8	11.8
40	6.8	17.6
41	6.2	11.4
42	5.4	19.2
43	6.8	12.2
44	10.9	19.9
45	14.2	16.6
46	14.2	18.4
47	10.0	10.2
48	11.2	9.0
49	9.4	10.4
50	9.0	11.8
51	15.4	30.0
52	12.4	31.8
53	10.1	13.1
54	16.4	20.4
55	19.6	20.6
56	16.6	23.8
57	13.8	15.8
58	10.4	21.2
59	7.6	14.2
60	13.4	20.6
Mean	**11.3**	**17.7**
St Dev	4.4	7.0

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.68	-0.44	0.64	**0.60 – 0.69**
St Dev	0.21	0.34		

With respect to WBC concentration at t=4hr, the 90% confidence interval does not exclude values < 0.80.

Table 9.5: Red Blood Cell Concentration (RBC x 10^9/mL)**, 0hr**

Sample ID	Test	Predicate
1	0.13	0.64
2	0.14	0.69
3	0.10	0.88
4	0.18	0.66
5	0.16	0.96
6	0.13	1.80
7	0.10	0.97
8	0.16	0.74
9	0.24	0.82
10	0.16	1.06
11	0.16	0.70
12	0.23	0.73
13	0.09	0.76
14	0.29	1.21
15	0.25	1.01
16	0.20	1.22
17	0.29	0.76
18	0.20	0.72
19	0.24	0.62
20	0.39	0.90
21	0.26	2.38
22	0.11	0.99
23	0.32	1.10
24	0.16	0.62
25	0.20	1.32
26	0.29	0.98
27	0.16	0.80
28	0.33	1.15
29	0.13	0.80
30	0.16	0.88
31	0.22	0.70
32	0.35	0.70
33	0.12	0.80
34	0.12	1.41
35	0.16	0.98
36	0.10	0.86
37	0.26	0.68
38	0.34	0.76

Sample ID	Test	Predicate
39	0.24	0.99
40	0.14	1.00
41	0.16	0.96
42	0.20	0.94
43	0.10	0.84
44	0.21	1.02
45	0.18	0.86
46	0.20	0.68
47	0.21	0.58
48	0.10	0.66
49	0.24	0.86
50	0.20	0.60
51	0.24	0.72
52	0.26	0.82
53	0.19	0.92
54	0.24	0.62
55	0.28	0.64
56	0.26	0.67
57	0.18	1.00
58	0.22	0.62
59	0.22	0.98
60	0.16	0.84
Mean	**0.20**	**0.89**
St Dev	0.07	0.29

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.24	-1.51	0.22	**0.20 – 0.24**
St Dev	0.10	0.45		

With respect to RBC concentration at t=0hr, the 90% confidence interval does not exclude values < 0.80.

Table 9.6: Red Blood Cell Concentration (RBC x 10^9/mL)**, 4hr**

Sample ID	Test	Predicate
1	0.13	0.66
2	0.14	0.69
3	0.10	0.90
4	0.18	0.68
5	0.16	1.02
6	0.14	1.77
7	0.08	0.96
8	0.16	0.74
9	0.24	0.80
10	0.16	1.06
11	0.16	0.68
12	0.23	0.70
13	0.09	0.74
14	0.29	1.22
15	0.26	1.02
16	0.18	1.20
17	0.30	0.76
18	0.20	0.68
19	0.22	0.64
20	0.39	0.90
21	0.28	2.38
22	0.11	1.01
23	0.32	1.16
24	0.16	0.62
25	0.18	1.29
26	0.28	0.96
27	0.14	0.80
28	0.31	1.18
29	0.12	0.78
30	0.16	0.92
31	0.20	0.68
32	0.35	0.69
33	0.12	0.78
34	0.12	1.41
35	0.14	0.98
36	0.08	0.92
37	0.24	0.66
38	0.38	0.82

Sample ID	Test	Predicate
39	0.26	1.04
40	0.14	0.98
41	0.16	0.96
42	0.20	0.98
43	0.10	0.88
44	0.20	1.02
45	0.18	0.90
46	0.18	0.66
47	0.20	0.58
48	0.10	0.66
49	0.24	0.86
50	0.20	0.64
51	0.24	0.74
52	0.26	0.82
53	0.18	0.90
54	0.26	0.62
55	0.26	0.67
56	0.26	0.70
57	0.18	1.00
58	0.22	0.66
59	0.22	1.00
60	0.14	0.78
Mean	**0.20**	**0.90**
St Dev	0.07	0.29

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.24	-1.54	0.21	**0.19 – 0.24**
St Dev	0.10	0.46		

With respect to RBC concentration at t=4hr, the 90% confidence interval does not exclude values < 0.80.

Table 9.7: Hematocrit (%), 0hr

Sample ID	Test	Predicate
1	1.3	6.1
2	1.2	5.6
3	0.8	7.4
4	1.6	6.0
5	1.2	8.2
6	1.0	13.2
7	0.8	8.2
8	1.4	7.0
9	2.2	7.6
10	1.2	8.4
11	1.6	6.8
12	1.9	6.1
13	0.7	5.6
14	2.6	11.0
15	1.9	8.4
16	1.6	9.8
17	3.1	8.0
18	2.0	7.0
19	1.8	5.0
20	3.6	8.4
21	2.4	23.8
22	0.8	7.9
23	3.0	10.2
24	1.6	5.6
25	1.6	10.5
26	2.9	9.3
27	1.4	7.0
28	2.7	9.5
29	1.4	8.4
30	1.4	7.8
31	2.2	7.0
32	2.9	6.2
33	1.2	7.6
34	1.0	11.9
35	1.2	7.6
36	0.8	7.6
37	2.4	6.6
38	2.8	6.8

Sample ID	Test	Predicate
39	1.6	7.0
40	1.2	9.0
41	1.2	7.2
42	1.6	7.8
43	0.8	6.8
44	1.8	8.4
45	1.4	7.2
46	1.8	6.4
47	1.8	5.1
48	1.0	6.0
49	2.2	7.8
50	2.0	6.0
51	2.2	6.6
52	2.4	7.6
53	1.7	7.9
54	2.2	5.6
55	2.4	5.6
56	2.4	6.1
57	1.6	8.6
58	1.8	5.6
59	1.6	7.4
60	1.4	7.4
Mean	**1.8**	**7.8**
St Dev	0.7	2.6

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.24	-1.53	0.22	**0.20 – 0.24**
St Dev	0.10	0.45		

With respect to Hematocrit at t=0hr, the 90% confidence interval does not exclude values < 0.80.

Table 9.8: Hematocrit (%), 4hr

Sample ID	Test	Predicate
1	1.3	6.4
2	1.2	5.7
3	0.8	7.4
4	1.6	6.0
5	1.2	9.0
6	1.0	12.3
7	0.8	8.1
8	1.4	7.0
9	2.2	7.2
10	1.2	8.6
11	1.6	6.6
12	1.9	5.9
13	0.7	5.4
14	2.7	11.3
15	2.0	8.4
16	1.6	9.4
17	3.2	7.9
18	2.0	6.6
19	1.8	5.2
20	3.9	8.6
21	2.6	24.0
22	0.8	8.1
23	3.0	10.4
24	1.4	5.6
25	1.0	10.5
26	2.7	9.2
27	1.2	6.8
28	2.6	9.8
29	1.4	8.2
30	1.4	8.0
31	2.2	6.8
32	2.9	6.1
33	1.2	7.2
34	1.0	11.8
35	1.2	7.6
36	0.8	8.2
37	2.4	6.2
38	3.4	7.0

Sample ID	Test	Predicate
39	1.6	7.2
40	1.2	8.6
41	1.2	7.0
42	1.6	8.0
43	0.8	7.2
44	1.6	8.4
45	1.4	7.2
46	1.8	6.2
47	1.8	5.2
48	1.0	6.1
49	2.2	7.8
50	2.0	6.2
51	2.2	6.8
52	2.4	7.4
53	1.6	7.8
54	2.2	5.6
55	2.4	5.8
56	2.2	6.4
57	1.6	8.4
58	1.8	6.0
59	1.6	7.2
60	1.4	7.0
Mean	**1.7**	**7.8**
St Dev	0.7	2.6

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.24	-1.54	0.21	**0.19 – 0.24**
St Dev	0.10	0.46		

With respect to Hematocrit at t=4hr, the 90% confidence interval does not exclude values < 0.80.

Table 9.9: Platelet Concentration (Platelets x 10^6 cells/mL), 0hr

Sample ID	Test	Predicate
1	900	789
2	1116	671
3	1276	1114
4	1122	1644
5	1542	1216
6	642	1422
7	774	733
8	1400	1352
9	1120	1196
10	1880	1852
11	1340	1054
12	756	820
13	989	1268
14	831	633
15	973	536
16	1184	1182
17	801	877
18	1734	1440
19	1630	1642
20	2151	1492
21	824	990
22	732	525
23	1646	1206
24	1114	1096
25	1890	1896
26	981	761
27	1502	1334
28	695	665
29	923	961
30	1486	1174
31	1542	1420
32	941	955
33	1256	1296
34	1276	797
35	1480	1226
36	1156	1264
37	1416	1484
38	1330	1410

Sample ID	Test	Predicate
39	862	647
40	1012	1060
41	1126	1102
42	1110	1058
43	1138	1274
44	713	580
45	1626	1160
46	1478	1616
47	737	745
48	1216	914
49	1410	1258
50	1632	1472
51	1872	1944
52	1114	958
53	860	980
54	1348	1556
55	1626	759
56	1296	953
57	1198	1044
58	1476	1548
59	1040	1174
60	1296	1148
Mean	**1226**	**1139**
St Dev	344	341

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	1.11	0.08	1.08	**1.03 – 1.14**
St Dev	0.27	0.23		

With respect to PLT concentration at t=0hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.10: Platelet Concentration (Platelets x 10^6 cells/mL), 4hr

Sample ID	Test	Predicate
1	854	821
2	1142	675
3	1268	1092
4	1112	1654
5	1558	1280
6	725	1431
7	739	738
8	1358	1348
9	1168	1192
10	1894	1910
11	1382	1106
12	756	825
13	993	1246
14	783	598
15	1124	556
16	1122	1198
17	803	839
18	1778	1468
19	1692	1642
20	2355	1520
21	808	1012
22	715	535
23	1648	1176
24	1088	1114
25	2241	2094
26	988	751
27	1492	1352
28	653	655
29	926	957
30	1522	1242
31	1518	1432
32	931	972
33	1130	1164
34	1066	792
35	1340	1244
36	1092	1258
37	1414	1524
38	1370	1468

Sample ID	Test	Predicate
39	808	670
40	1022	1026
41	1142	1172
42	1080	1126
43	1106	1284
44	722	572
45	1598	1146
46	1414	1574
47	721	742
48	1170	854
49	1286	1214
50	1512	1460
51	1796	1972
52	1140	938
53	835	940
54	1314	1576
55	1478	723
56	1310	966
57	1178	1018
58	1470	1558
59	1058	1140
60	1264	1154
Mean	**1216**	**1145**
St Dev	365	356

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	1.10	0.07	1.07	**1.02 – 1.12**
St Dev	0.27	0.23		

With respect to PLT concentration at t=4hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.11: Platelet Concentration Factor (x baseline), 0hr

Sample ID	Test	Predicate
1	5.4	4.7
2	6.0	3.6
3	6.4	5.6
4	4.2	6.1
5	7.7	6.0
6	2.7	5.9
7	6.3	6.0
8	6.9	6.7
9	5.5	5.9
10	6.4	6.3
11	5.4	4.2
12	7.2	7.8
13	5.1	6.6
14	5.6	4.3
15	5.1	2.8
16	6.3	6.3
17	5.4	5.9
18	6.1	5.0
19	5.4	5.4
20	6.9	4.8
21	7.8	9.4
22	6.6	4.8
23	7.7	5.7
24	6.4	6.3
25	5.6	5.6
26	6.1	4.8
27	6.8	6.0
28	5.5	5.2
29	5.5	5.7
30	6.0	4.8
31	5.8	5.3
32	6.6	6.7
33	6.3	6.5
34	6.7	4.2
35	5.8	4.8
36	5.4	5.9
37	6.5	6.8

Sample ID	Test	Predicate
38	6.0	6.4
39	7.3	5.5
40	6.1	6.4
41	4.2	4.2
42	6.7	6.4
43	5.2	5.8
44	6.1	4.9
45	7.1	5.1
46	5.5	6.0
47	5.1	5.1
48	6.4	4.8
49	6.7	6.0
50	6.4	5.8
51	6.5	6.8
52	6.9	5.9
53	4.6	5.3
54	4.4	5.1
55	8.0	3.7
56	7.2	5.3
57	5.6	4.9
58	5.7	6.0
59	5.7	6.4
60	6.7	6.0
Mean	**6.0**	**5.6**
St Dev	1.0	1.0

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	1.11	0.08	1.08	**1.03 – 1.14**
St Dev	0.27	0.23		

With respect to PLT concentration factor at t=0hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.12: Platelet Concentration Factor (x baseline), 4hr

Sample ID	Test	Predicate
1	5.1	4.9
2	6.1	3.6
3	6.3	5.5
4	4.1	6.1
5	7.7	6.4
6	3.0	5.9
7	6.0	6.0
8	6.7	6.7
9	5.7	5.9
10	6.5	6.5
11	5.6	4.5
12	7.2	7.8
13	5.2	6.5
14	5.3	4.0
15	5.9	2.9
16	5.9	6.3
17	5.4	5.6
18	6.2	5.1
19	5.6	5.4
20	7.5	4.9
21	7.7	9.6
22	6.5	4.8
23	7.7	5.5
24	6.2	6.4
25	6.6	6.2
26	6.2	4.7
27	6.7	6.1
28	5.1	5.1
29	5.5	5.7
30	6.2	5.0
31	5.7	5.4
32	6.5	6.8
33	5.7	5.8
34	5.6	4.1
35	5.2	4.8
36	5.1	5.9
37	6.5	7.0
38	6.2	6.6

Sample ID	Test	Predicate
39	6.8	5.7
40	6.2	6.2
41	4.3	4.4
42	6.5	6.8
43	5.0	5.8
44	6.1	4.9
45	7.0	5.0
46	5.2	5.8
47	5.0	5.1
48	6.1	4.5
49	6.1	5.8
50	5.9	5.7
51	6.2	6.9
52	7.1	5.8
53	4.5	5.1
54	4.3	5.2
55	7.3	3.6
56	7.3	5.4
57	5.5	4.8
58	5.7	6.0
59	5.8	6.2
60	6.6	6.0
Mean	**6.0**	**5.6**
St Dev	0.9	1.0

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	1.10	0.07	1.07	**1.02 – 1.12**
St Dev	0.27	0.23		

With respect to PLT concentration factor at t=4hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.13: Platelet Yield (%), 0hr

Sample ID	Test	Predicate
1	71	53
2	77	40
3	74	67
4	55	74
5	89	73
6	38	71
7	79	74
8	97	81
9	72	77
10	81	78
11	76	49
12	102	91
13	64	79
14	77	51
15	66	34
16	74	75
17	76	71
18	81	61
19	72	65
20	69	56
21	105	109
22	94	59
23	85	68
24	78	77
25	72	68
26	82	58
27	90	72
28	73	63
29	71	70
30	85	57
31	81	64
32	83	81
33	84	78
34	91	50
35	77	58
36	73	72
37	73	87
38	75	81

Sample ID	Test	Predicate
39	85	66
40	86	77
41	55	50
42	91	78
43	69	71
44	83	60
45	85	63
46	85	76
47	68	63
48	81	61
49	76	71
50	85	71
51	81	82
52	87	72
53	46	66
54	48	64
55	95	46
56	97	65
57	68	59
58	74	76
59	80	82
60	86	75
Mean	**78**	**68**
St Dev	13	12

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	1.18	0.14	1.15	**1.08 – 1.22**
St Dev	0.29	0.24		

With respect to PLT Yield at t=0hr, the 95% confidence interval excludes values < 0.80 and >1.25.

Table 9.14: Platelet Yield (%), 4hr

Sample ID	Test	Predicate
1	68	55
2	78	40
3	74	66
4	54	74
5	90	77
6	42	71
7	75	74
8	94	80
9	76	77
10	82	80
11	79	52
12	102	91
13	64	78
14	73	49
15	76	35
16	70	77
17	77	68
18	83	62
19	74	65
20	75	57
21	103	111
22	92	60
23	85	67
24	76	78
25	85	75
26	82	57
27	89	73
28	68	62
29	71	70
30	87	61
31	80	65
32	82	82
33	76	70
34	76	50
35	70	59
36	69	71
37	72	89
38	77	85

Sample ID	Test	Predicate
39	80	69
40	87	75
41	56	53
42	88	84
43	67	71
44	84	59
45	84	62
46	81	74
47	66	62
48	78	57
49	70	69
50	79	71
51	78	83
52	89	70
53	45	63
54	47	64
55	86	43
56	98	66
57	67	58
58	74	76
59	82	79
60	84	75
Mean	**77**	**68**
St Dev	12	13

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	1.16	0.12	1.13	**1.07 – 1.20**
St Dev	0.29	0.24		

With respect to PLT Yield at t=4hr, the 95% confidence interval excludes values < 0.80 and >1.25.

Table 9.15: pH, 0hr

Sample ID	Test	Predicate
1	**6.8**	**7.3**
2	**6.9**	**7.2**
3	**7.1**	**7.3**
4	**6.7**	**7.2**
11	**6.7**	**7.2**
12	**6.5**	**7.3**
13	**6.6**	**7.1**
14	**6.7**	**7.1**
15	**6.7**	**7.2**
16	**6.6**	**7.2**
17	**6.6**	**7.1**
18	**7.0**	**7.2**
19	**6.7**	**7.2**
20	**7.0**	**7.2**
21	**7.1**	**7.2**
22	**6.9**	**7.1**
23	**6.5**	**7.0**
24	**6.6**	**7.2**
25	**6.9**	**7.2**
26	**6.7**	**7.1**
27	**6.9**	**7.2**
28	**6.6**	**7.1**
29	**6.7**	**7.1**
30	**6.8**	**7.1**
31	**6.7**	**7.2**
32	**6.6**	**7.1**
Mean	**6.8**	**7.2**
St Dev	0.2	0.1

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.94	-0.06	0.94	**0.94 – 0.95**
St Dev	0.02	0.02		

With respect to pH at t=0hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.16: pH, 4hr

Sample ID	Test	Predicate
1	**6.9**	**7.4**
2	**7.0**	**7.3**
3	**7.1**	**7.3**
4	**6.9**	**7.3**
11	**6.8**	**7.2**
12	**6.6**	**7.3**
13	**6.7**	**7.2**
14	**6.9**	**7.2**
15	**6.8**	**7.2**
16	**6.6**	**7.2**
17	**6.7**	**7.2**
18	**7.1**	**7.2**
19	**6.8**	**7.3**
20	**7.1**	**7.2**
21	**7.2**	**7.2**
22	**7.0**	**7.2**
23	**6.6**	**7.1**
24	**6.7**	**7.3**
25	**6.9**	**7.2**
26	**6.8**	**7.2**
27	**7.0**	**7.3**
28	**6.7**	**7.2**
29	**6.8**	**7.1**
30	**6.8**	**7.1**
31	**6.8**	**7.2**
32	**6.7**	**7.1**
Mean	**6.9**	**7.2**
St Dev	0.2	0.1

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.95	-0.05	0.95	**0.94 – 0.96**
St Dev	0.02	0.02		

With respect to pH at t=4hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.17: Platelet Activation, Resting 0hr (%p-Selectin expression)

Sample ID	Baseline	Test	Predicate
30	3.3	4.9	4.6
31	5.6	8.3	7.8
32	3.7	3.3	7.5
33	2.9	4.2	4.0
34	5.1	10.2	11.0
35	4.2	8.3	9.1
36	1.9	3.9	2.1
37	1.8	2.1	2.5
38	1.1	1.4	2.0
39	1.9	3.0	3.5
40	3.4	6.8	7.2
41	2.4	3.4	3.1
Mean	**3.1**	**5.0**	**5.4**
St Dev	1.3	2.6	2.9

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.98	-0.07	0.93	**0.80 – 1.08**
St Dev	0.32	0.32		

With respect to Platelet activation under resting conditions at t=0hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.18: Platelet Activation, Resting 4hr (%p-Selectin expression)

Sample ID	Test	Predicate
30	4.4	6.2
31	9.0	8.3
32	4.6	5.0
33	5.4	7.0
34	9.1	14.1
35	10.6	8.9
36	4.4	3.6
37	7.4	6.9
38	3.8	5.1
39	7.0	9.7
40	8.6	13.9
41	2.9	3.5
Mean	**6.4**	**7.7**
St Dev	2.4	3.4

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.88	-0.16	0.85	**0.77 – 0.95**
St Dev	0.20	0.23		

With respect to Platelet activation under resting conditions at t=4hr, the 90% LCB does not exclude values < 0.80.

Table 9.19: Platelet Activation, ADP-Stimulated 0hr (%p-Selectin expression)

Sample ID	Baseline	Test	Predicate
30	98.9	99.2	98.9
31	98.0	98.4	98.4
32	98.6	98.8	98.8
33	96.9	97.9	98.6
34	95.8	96.5	97.3
35	94.7	95.4	96.2
36	98.2	98.4	98.2
37	95.9	97.1	98.2
38	97.6	97.8	98.0
39	97.5	97.7	97.7
40	97.1	97.0	97.4
41	95.8	96.1	96.9
Mean	**97.1**	**97.5**	**97.9**
St Dev	1.3	1.1	0.8

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.996	-0.004	0.996	**0.994 – 0.998**
St Dev	0.005	0.005		

With respect to ADP-Stimulated Platelet activation at t=0hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.20: Platelet Activation, ADP-Stimulated 4hr (%p-Selectin expression)

Sample ID	Test	Predicate
30	99.0	98.9
31	98.0	97.7
32	98.2	98.7
33	97.6	98.1
34	96.6	97.1
35	95.2	95.6
36	98.5	98.4
37	97.0	97.7
38	98.0	98.0
39	97.8	97.5
40	97.0	97.2
41	95.3	96.6
Mean	**97.3**	**97.6**
St Dev	1.1	0.9

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.997	-0.003	0.997	**0.995 – 0.999**
St Dev	0.005	0.005		

With respect to ADP-Stimulated Platelet activation at t=4hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.21: Platelet Aggregation (%), 0hr

Sample ID	Test	Predicate
2	70	75
3	76	82
7	78	82
14	72	80
15	61	73
23	64	65
45	71	64
46	63	79
49	59	66
50	71	66
51	69	63
52	71	75
Mean	**69**	**73**
St Dev	6	7

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.95	-0.05	0.95	**0.91 – 0.99**
St Dev	0.09	0.10		

With respect to Platelet Aggregation at t=0hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.22: Platelet Aggregation, 4hr

Sample ID	Test	Predicate
2	71	78
3	63	74
7	70	80
14	83	75
15	70	76
23	68	70
45	74	64
46	63	75
49	65	75
50	61	68
51	70	66
52	76	78
Mean	**70**	**73**
St Dev	6	5

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	0.95	-0.05	0.95	**0.90 – 0.99**
St Dev	0.10	0.10		

With respect to Platelet Aggregation at t=4hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.23: Hypotonic Stress Response, 0hr

Sample ID	Test	Predicate
2	91	85
3	76	93
7	61	39
8	68	64
14	81	73
15	82	76
16	60	83
17	89	91
26	75	82
27	88	94
28	77	76
29	88	94
Mean	**78**	**79**
St Dev	10	15

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	1.02	-0.001	1.00	**0.92 – 1.09**
St Dev	0.20	0.18		

With respect to Hypotonic Stress Response at t=0hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.24: Hypotonic Stress Response, 4hr

Sample ID	Test	Predicate
2	75	54
3	62	59
7	43	35
8	44	49
14	75	55
15	81	62
16	61	74
17	74	94
26	80	69
27	102	82
28	77	69
29	78	75
Mean	**71**	**65**
St Dev	16	15

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	1.12	0.10	1.10	**1.01 – 1.20**
St Dev	0.19	0.18		

With respect to Hypotonic Stress Response at t=4hr, the 90% confidence interval excludes values < 0.80 and >1.25.

Table 9.25: Bone Graft Retention

Sample ID	% Recovery		Ratio to Control	
	Test	Predicate	Test	Predicate
45	80	88	6.9	7.6
46	76	86	6.6	7.4
47	78	82	6.8	7.1
48	86	86	7.4	7.4
49	84	62	7.3	5.4
50	94	88	8.1	7.6
51	88	76	7.6	6.6
52	78	70	6.8	6.1
53	82	96	7.1	8.3
54	90	78	7.8	6.8
55	88	86	7.6	7.4
56	88	68	7.6	5.9
Mean	**85**	**81**	**7.3**	**7.0**
St Dev	5	9	0.5	0.8

	Ratio (T/P)	Ln(Ratio)	EXP (Mean Ln(T/P))	Confidence Interval
Mean	1.06	0.05	1.05	**0.99 – 1.13**
St Dev	0.15	0.14		

With respect to Bone Graft Retention, the 90% confidence interval excludes values < 0.80 and >1.25