


Test Report
PN1808

Equivalence Testing: Healeon Medical Inc 15mL and 30mL PRP tubes vs. Predicate Device

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Table 9.1.1 Hematology Data: Baseline – 15mL Test

WBC – White Blood Cells; RBC – Red Blood Cells; PLT – Platelets; Htc – Hematocrit

Donor Number	WBC x 10 ⁶ cells/mL	PLT x 10 ⁶ cells/mL	RBC x 10 ⁹ cells/mL	Htc %
1	5.5	353	4.10	38.2
2	4.2	202	4.22	38.0
3	4.6	270	4.57	38.7
4	4.7	158	3.90	37.3
5	4.4	194	4.60	39.1
6	5.1	266	3.60	32.3
7	5.1	238	4.34	34.1
8	3.6	172	3.92	37.1
9	5.5	248	4.98	37.6
10	9.7	263	4.61	36.7
11	4.9	231	3.99	33.0
12	3.2	139	5.46	39.6
13	6.3	290	4.01	29.0
14	3.3	92	4.30	38.3
15	4.6	179	4.26	29.8
Mean	5.0	219	4.32	35.9
St Dev	1.5	64	0.45	3.3

Table 9.1.2 Hematology Data: Baseline – 30mL Test

Donor Number	WBC x 10 ⁶ cells/mL	PLT x 10 ⁶ cells/mL	RBC x 10 ⁹ cells/mL	Htc %
1	5.5	293	4.06	38.2
2	4.5	132	4.09	36.8
3	4.6	281	4.48	37.8
4	4.8	157	3.93	37.5
5	4.6	185	4.75	40.2
6	5.2	257	3.63	32.1
7	5.1	242	4.19	32.6
8	3.5	169	3.86	36.5
9	5.5	203	4.29	32.2
10	9.8	236	4.52	36.1
11	5.0	208	3.97	32.4
12	3.1	132	5.19	38.0
13	6.3	339	3.97	28.8
14	3.4	95	4.28	37.9
15	4.5	182	3.95	27.6
Mean	5.0	207	4.21	35.0
St Dev	1.5	65	0.38	3.6

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Table 9.1.3 Hematology Data: Baseline – Predicate

Donor Number	WBC x 10 ⁶ cells/mL	PLT x 10 ⁶ cells/mL	RBC x 10 ⁹ cells/mL	Htc %
1	5.5	313	3.82	35.8
2	4.3	179	4.11	37.4
3	4.8	272	4.42	37.7
4	4.7	143	3.89	37.2
5	4.6	179	4.73	40.2
6	5.0	248	3.57	32.1
7	5.0	230	4.30	33.5
8	3.7	167	3.90	37.0
9	5.7	206	4.77	36.0
10	9.9	227	4.62	37.0
11	4.8	237	4.02	33.3
12	3.1	123	5.39	39.2
13	6.3	305	3.97	28.8
14	3.3	92	4.30	38.4
15	4.8	187	4.13	28.9
Mean	5.0	207	4.26	35.5
St Dev	1.5	61	0.45	3.4

Table 9.2.1 Hematology Data: Product – 15mL Test

Donor Number	WBC x 10 ⁶ cells/mL		RBC x 10 ⁹ cells/mL		Htc %	
	0hr	4hr	0hr	4hr	0hr	4hr
1	0.3	0.3	0.01	0.00	0.1	0.0
2	0.3	0.3	0.00	0.00	0.0	0.0
3	0.8	0.8	0.01	0.01	0.0	0.1
4	0.3	0.1	0.00	0.00	0.0	0.0
5	0.3	0.2	0.00	0.01	0.0	0.1
6	0.3	0.2	0.01	0.00	0.0	0.0
7	0.2	0.2	0.00	0.00	0.0	0.0
8	0.3	0.2	0.01	0.00	0.0	0.0
9	0.5	0.4	0.02	0.01	0.1	0.0
10	0.3	0.3	0.01	0.01	0.0	0.0
11	0.3	0.3	0.01	0.00	0.1	0.0
12	0.7	0.3	0.02	0.02	0.2	0.1
13	0.3	0.2	0.01	0.01	0.1	0.1
14	0.3	0.3	0.01	0.01	0.1	0.1
15	0.3	0.3	0.01	0.01	0.1	0.0
Mean	0.4	0.3	0.01	0.01	0.1	0.0
St Dev	0.2	0.2	0.01	0.01	0.1	0.0

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Table 9.2.2 Hematology Data: Product – 30mL Test

Donor Number	WBC x 10 ⁶ cells/mL		RBC x 10 ⁹ cells/mL		Htc %	
	0hr	4hr	0hr	4hr	0hr	4hr
1	0.4	0.3	0.00	0.00	0.0	0.0
2	0.3	0.3	0.00	0.00	0.0	0.0
3	0.5	0.5	0.02	0.01	0.2	0.1
4	0.2	0.3	0.01	0.01	0.1	0.1
5	0.5	0.5	0.01	0.01	0.1	0.1
6	0.2	0.2	0.00	0.00	0.0	0.0
7	0.3	0.3	0.01	0.01	0.0	0.0
8	0.2	0.2	0.00	0.00	0.0	0.0
9	0.4	0.4	0.01	0.01	0.1	0.0
10	0.6	0.5	0.01	0.01	0.0	0.1
11	0.2	0.1	0.00	0.00	0.0	0.0
12	0.2	0.2	0.00	0.00	0.0	0.0
13	0.2	0.2	0.01	0.01	0.0	0.0
14	0.3	0.3	0.01	0.01	0.1	0.0
15	0.3	0.3	0.01	0.01	0.0	0.1
Mean	0.3	0.3	0.01	0.01	0.0	0.0
St Dev	0.1	0.1	0.01	0.00	0.1	0.0

Table 9.2.3 Hematology Data: Product – Predicate

Donor Number	WBC x 10 ⁶ cells/mL		RBC x 10 ⁹ cells/mL		Htc %	
	0hr	4hr	0hr	4hr	0hr	4hr
1	0.3	0.2	0.00	0.00	0.0	0.0
2	0.1	0.2	0.00	0.00	0.0	0.0
3	0.2	0.2	0.01	0.01	0.0	0.0
4	0.2	0.2	0.00	0.00	0.0	0.0
5	0.2	0.2	0.00	0.01	0.0	0.0
6	0.2	0.2	0.00	0.00	0.0	0.0
7	0.2	0.1	0.00	0.00	0.0	0.0
8	0.2	0.1	0.00	0.00	0.0	0.0
9	0.2	0.1	0.01	0.01	0.0	0.0
10	0.2	0.2	0.01	0.00	0.0	0.0
11	0.2	0.2	0.01	0.01	0.0	0.0
12	0.3	0.3	0.01	0.01	0.1	0.1
13	0.1	0.1	0.00	0.00	0.0	0.0
14	0.2	0.2	0.00	0.01	0.0	0.0
15	0.2	0.3	0.01	0.01	0.0	0.0
Mean	0.2	0.2	0.00	0.00	0.0	0.0
St Dev	0.1	0.1	0.00	0.00	0.0	0.0

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Table 9.9 Product pH, 0hr

Donor Number	Test - 15mL	Test - 30mL	Predicate
1	7.66	7.65	7.56
2	7.66	7.64	7.58
3	7.60	7.56	7.46
4	7.68	7.57	7.51
5	7.64	7.61	7.62
6	7.65	7.63	7.62
7	7.59	7.61	7.55
8	7.62	7.60	7.62
9	7.60	7.69	7.55
10	7.56	7.57	7.50
11	7.57	7.50	7.50
12	7.58	7.65	7.57
13	7.52	7.53	7.42
14	7.53	7.53	7.47
15	7.55	7.55	7.45
Mean	7.60	7.59	7.53
St Dev	0.05	0.05	0.06

	15mL		30mL	
	Ratio (T/P)	Ln(Ratio)	Ratio (T/P)	Ln(Ratio)
Mean	1.01	0.009	1.01	0.008
StDev	0.01	0.006	0.01	0.006

15mL		30mL	
EXP (MeanLn(T/P))	Confidence Interval	EXP (MeanLn(T/P))	Confidence Interval
1.009	1.006 – 1.012	1.008	1.005 – 1.011

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Table 9.10 Product pH, 4hr

Donor Number	Test - 15mL	Test - 30mL	Predicate
1	7.71	7.71	7.63
2	7.72	7.76	7.63
3	7.66	7.67	7.59
4	7.73	7.68	7.66
5	7.67	7.68	7.68
6	7.73	7.70	7.67
7	7.67	7.66	7.61
8	7.70	7.68	7.67
9	7.62	7.74	7.63
10	7.65	7.65	7.61
11	7.66	7.67	7.60
12	7.66	7.66	7.62
13	7.61	7.64	7.53
14	7.65	7.68	7.58
15	7.65	7.76	7.55
Mean	7.67	7.69	7.62
St Dev	0.04	0.04	0.04

	15mL		30mL	
	Ratio (T/P)	Ln(Ratio)	Ratio (T/P)	Ln(Ratio)
Mean	1.01	0.007	1.01	0.009
StDev	0.004	0.004	0.01	0.007

15mL		30mL	
EXP (MeanLn(T/P))	Confidence Interval	EXP (MeanLn(T/P))	Confidence Interval
1.007	1.005 – 1.009	1.009	1.006 – 1.013

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Table 9.11 Resting Platelet Activation, 0hr

Donor Number	Baseline	Test - 15mL	Test - 30mL	Predicate
3	10.6%	5.5%	11.4%	8.2%
4	4.9%	3.9%	7.4%	4.5%
5	9.8%	9.9%	16.2%	15.9%
6	7.0%	5.8%	8.6%	12.2%
7	10.1%	4.6%	13.1%	10.4%
8	3.2%	2.3%	4.0%	5.3%
9	13.9%	6.8%	18.7%	7.4%
10	4.8%	4.4%	12.4%	6.2%
11	2.2%	2.6%	4.5%	3.5%
12	7.4%	4.9%	10.2%	7.9%
13	4.1%	5.6%	4.8%	6.1%
14	9.3%	2.9%	5.5%	3.4%
Mean	7.3%	4.9%	9.7%	7.6%
St Dev	3.4	2.0	4.6	3.6

	15mL		30mL	
	Ratio (T/P)	Ln(Ratio)	Ratio (T/P)	Ln(Ratio)
Mean	0.69	-0.41	1.36	0.23
StDev	0.17	0.27	0.52	0.38

15mL		30mL	
EXP (MeanLn(T/P))	Confidence Interval	EXP (MeanLn(T/P))	Confidence Interval
0.67	0.59 – 0.76	1.26	1.06 – 1.51

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Table 9.12 ADP Stimulated Platelet Activation, 0hr

Donor Number	Baseline	Test - 15mL	Test - 30mL	Predicate
3	96.5%	95.9%	96.1%	95.6%
4	97.1%	95.5%	96.8%	95.1%
5	95.8%	95.4%	93.2%	95.0%
6	95.8%	96.0%	96.0%	96.3%
7	96.2%	95.9%	95.4%	95.8%
8	96.4%	96.0%	95.5%	95.8%
9	95.3%	95.3%	95.5%	95.0%
10	92.1%	87.4%	93.6%	91.8%
11	97.6%	97.5%	96.5%	96.6%
12	95.8%	95.7%	94.4%	93.9%
13	98.3%	97.5%	98.1%	97.5%
14	93.1%	89.0%	89.7%	87.4%
Mean	95.8%	94.8%	95.1%	94.7%
St Dev	1.7	3.0	2.1	2.6

	15mL		30mL	
	Ratio (T/P)	Ln(Ratio)	Ratio (T/P)	Ln(Ratio)
Mean	1.00	0.001	1.00	0.004
StDev	0.02	0.016	0.01	0.012

15mL		30mL	
EXP (MeanLn(T/P))	Confidence Interval	EXP (MeanLn(T/P))	Confidence Interval
1.00	0.99 – 1.01	1.00	1.00 – 1.01

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Table 9.13 Resting Platelet Activation, 4hr

Donor Number	Test - 15mL	Test - 30mL	Predicate
3	9.3%	24.0%	11.9%
4	9.8%	22.8%	8.1%
5	14.4%	32.6%	17.4%
6	19.7%	31.1%	19.8%
7	16.6%	34.9%	14.6%
8	11.7%	20.4%	8.8%
9	14.0%	45.9%	13.2%
10	10.2%	26.9%	11.4%
11	5.4%	19.9%	5.7%
12	20.0%	35.1%	16.8%
13	8.6%	15.3%	7.6%
14	24.8%	35.6%	21.7%
Mean	13.7%	28.7%	13.1%
St Dev	5.4	8.3	4.9

	15mL		30mL	
	Ratio (T/P)	Ln(Ratio)	Ratio (T/P)	Ln(Ratio)
Mean	1.06	0.04	2.34	0.82
StDev	0.16	0.16	0.61	0.25

15mL		30mL	
EXP (MeanLn(T/P))	Confidence Interval	EXP (MeanLn(T/P))	Confidence Interval
1.04	0.97 – 1.12	2.27	2.02 – 2.55

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Table 9.14 ADP Stimulated Platelet Activation, 4hr

Donor Number	Test - 15mL	Test - 30mL	Predicate
3	93.8%	95.1%	94.2%
4	94.7%	96.2%	94.0%
5	95.8%	93.5%	93.1%
6	95.9%	95.0%	94.9%
7	95.5%	95.1%	94.5%
8	95.9%	95.8%	94.5%
9	94.9%	94.6%	94.6%
10	93.6%	92.8%	91.5%
11	96.9%	96.1%	96.7%
12	95.5%	94.5%	93.3%
13	95.5%	96.4%	96.3%
14	92.5%	92.4%	91.3%
Mean	95.0%	94.8%	94.0%
St Dev	1.2	1.3	1.6

	15mL		30mL	
	Ratio (T/P)	Ln(Ratio)	Ratio (T/P)	Ln(Ratio)
Mean	1.01	0.01	1.01	0.01
StDev	0.01	0.01	0.01	0.01

15mL		30mL	
EXP (MeanLn(T/P))	Confidence Interval	EXP (MeanLn(T/P))	Confidence Interval
1.01	1.01 – 1.02	1.01	1.00 – 1.01