

Supplemental Table (Table 3). Number of subjects with safety parameters that were above or below the reference ranges at screening and day 21(or end of study visit for those who dropped from the study).

	Reference Range Site 1 / Site2	Screening		Day 21		P-value
		Number of Men Below Range	Number of Men Above Range	Number of Men Below Range	Number of Men Above Range	
Total Cholesterol (mg/dL) ^a	118 - 275	1	3	4	2	0.34
HDL Cholesterol (mg/dL) ^a	40 - 59	52	17	80	6	<0.0001
LDL Cholesterol (mg/dL) ^a	80 - 179	15	9	18	5	0.21
Triglycerides (mg/dL) ^a	40 - 160	15	23	12	19	0.50
PSA (ng/mL) ^a	0 - 4	0	0	0	0	1.00
ALP (IU/L)	38 – 126 / 35 - 109	2	1	2	1	1.00
ALT (IU/L)	17 – 63 / 12 - 79	6	9	10	2	0.03
AST (IU/L)	15 – 41 / 10 - 44	1	9	2	5	0.48
Urea Nitrogen (mg/dL)	8 – 20 / 8 - 21	6	2	7	1	0.80
Creatinine (mg/dL)	0.4 – 1.2 / 0.3 – 1.2	0	6	0	8	0.32
Hemoglobin (g/dL)	13.8 - 16.9 / 13 -18	3	4	4	1	0.20
Hematocrit (L/L)	39.9 - 50.4 / 38 - 50	3	2	3	1	0.85

^a Currently accepted ranges in healthy adult men were used for both centers.