表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（101/114）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			103.1	-0.3
SD			1.91	1.92
Minimum			98	-7
Q1			102.0	-1.0
Median			103.0	0.0
Q3			104.0	1.0
Maximum			107	4
Week 46				
N	0	0	87	87
Mean			103.1	-0.4
SD			2.30	2.18
Minimum			97	-6
Q1			102.0	-2.0
Median			103.0	0.0
Q3			105.0	1.0
Maximum			109	5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（102/114）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			103.1	-0.3
SD			1.96	1.76
Minimum			97	-4
Q1			102.0	-1.0
Median			103.0	0.0
Q3			104.0	1.0
Maximum			107	5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（103/114）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	9.16		9.20	
SD	0.318		0.314	
Minimum	8.4		8.4	
Q1	8.90		9.00	
Median	9.10		9.20	
Q3	9.40		9.40	
Maximum	10.0		10.2	
Week 3				
N	91	91	116	116
Mean	9.16	0.01	9.18	-0.03
SD	0.301	0.226	0.322	0.253
Minimum	8.4	-0.5	7.7	-0.7
Q1	9.00	-0.20	9.00	-0.20
Median	9.20	0.00	9.20	0.00
Q3	9.40	0.20	9.40	0.10
Maximum	10.1	0.5	10.0	0.8

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（104/114）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	9.12	-0.03	9.17	-0.03
SD	0.310	0.262	0.293	0.245
Minimum	8.5	-0.6	8.2	-0.6
Q1	8.90	-0.20	9.00	-0.20
Median	9.10	-0.10	9.20	0.00
Q3	9.30	0.10	9.30	0.10
Maximum	9.9	0.7	10.0	0.6
Week 14				
N	88	88	113	113
Mean	9.07	-0.07	9.11	-0.08
SD	0.291	0.276	0.321	0.268
Minimum	8.6	-0.6	8.1	-0.7
Q1	8.90	-0.30	8.90	-0.20
Median	9.10	-0.10	9.10	-0.10
Q3	9.20	0.10	9.30	0.10
Maximum	10.1	0.9	10.1	0.9

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（105/114）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	9.04	-0.10	9.08	-0.12
SD	0.290	0.277	0.321	0.270
Minimum	8.3	-0.6	8.4	-0.9
Q1	8.90	-0.30	8.90	-0.30
Median	9.10	-0.20	9.10	-0.10
Q3	9.20	0.10	9.30	0.10
Maximum	9.7	0.7	10.0	0.5
Week 26				
N	80	80	109	109
Mean	9.03	-0.11	9.07	-0.13
SD	0.323	0.273	0.305	0.301
Minimum	8.0	-0.8	8.3	-0.7
Q1	8.80	-0.30	8.90	-0.30
Median	9.00	-0.10	9.10	-0.20
Q3	9.20	0.10	9.30	0.00
Maximum	10.0	0.6	9.8	0.9

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（106/114）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	8.98	-0.23	9.06	-0.14
SD	0.320	0.126	0.320	0.277
Minimum	8.7	-0.4	8.4	-0.9
Q1	8.70	-0.30	8.80	-0.30
Median	8.95	-0.20	9.10	-0.10
Q3	9.25	-0.15	9.30	0.00
Maximum	9.3	-0.1	9.9	0.5
Week 32				
N	0	0	101	101
Mean			9.05	-0.16
SD			0.310	0.265
Minimum			8.1	-0.7
Q1			8.80	-0.30
Median			9.10	-0.20
Q3			9.30	0.00
Maximum			9.7	0.5

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（107/114）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			9.01	-0.18
SD			0.300	0.246
Minimum			8.3	-0.7
Q1			8.80	-0.40
Median			9.00	-0.20
Q3			9.30	0.00
Maximum			9.5	0.3
Week 46				
N	0	0	87	87
Mean			8.97	-0.21
SD			0.297	0.263
Minimum			8.3	-0.7
Q1			8.80	-0.40
Median			8.90	-0.20
Q3			9.20	0.00
Maximum			9.7	0.6

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（108/114）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			8.95	-0.24
SD			0.333	0.247
Minimum			7.3	-1.1
Q1			8.80	-0.30
Median			9.00	-0.20
Q3			9.20	-0.10
Maximum			9.7	0.3

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（109/114）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Baseline				
N	95		117	
Mean	3.38		3.41	
SD	0.409		0.409	
Minimum	2.2		2.4	
Q1	3.10		3.10	
Median	3.40		3.40	
Q3	3.70		3.70	
Maximum	4.4		4.5	
Week 3				
N	91	91	116	116
Mean	3.39	0.00	3.36	-0.04
SD	0.385	0.284	0.419	0.311
Minimum	2.3	-0.9	2.4	-1.1
Q1	3.10	-0.20	3.10	-0.20
Median	3.40	0.00	3.40	-0.10
Q3	3.60	0.20	3.60	0.20
Maximum	4.3	0.9	4.5	0.9

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（110/114）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 6				
N	92	92	114	114
Mean	3.34	-0.04	3.40	-0.01
SD	0.430	0.323	0.406	0.332
Minimum	2.1	-0.7	2.6	-1.1
Q1	3.10	-0.30	3.10	-0.20
Median	3.40	-0.10	3.40	0.00
Q3	3.60	0.20	3.70	0.20
Maximum	4.1	0.8	4.4	0.7
Week 14				
N	88	88	113	113
Mean	3.37	-0.01	3.39	-0.02
SD	0.428	0.295	0.425	0.336
Minimum	2.2	-0.7	2.1	-1.1
Q1	3.10	-0.20	3.10	-0.20
Median	3.40	0.10	3.40	0.00
Q3	3.70	0.20	3.60	0.30
Maximum	4.2	0.7	4.3	0.6

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（111/114）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 20				
N	85	85	111	111
Mean	3.33	-0.05	3.41	0.01
SD	0.403	0.371	0.431	0.377
Minimum	2.6	-1.2	2.3	-1.0
Q1	3.00	-0.20	3.10	-0.30
Median	3.40	0.00	3.40	0.00
Q3	3.50	0.10	3.70	0.30
Maximum	4.4	1.0	4.7	0.8
Week 26				
N	80	80	109	109
Mean	3.40	0.01	3.37	-0.03
SD	0.410	0.355	0.420	0.335
Minimum	2.5	-0.7	2.3	-1.0
Q1	3.10	-0.25	3.10	-0.20
Median	3.35	0.00	3.40	0.00
Q3	3.75	0.30	3.60	0.20
Maximum	4.2	0.9	4.6	0.6

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（112/114）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 29				
N	4	4	103	103
Mean	3.10	-0.05	3.34	-0.04
SD	0.356	0.342	0.411	0.366
Minimum	2.6	-0.4	2.3	-1.4
Q1	2.85	-0.30	3.10	-0.20
Median	3.20	-0.10	3.40	-0.10
Q3	3.35	0.20	3.60	0.20
Maximum	3.4	0.4	4.3	0.7
Week 32				
N	0	0	101	101
Mean			3.33	-0.06
SD			0.435	0.333
Minimum			2.3	-1.0
Q1			3.00	-0.20
Median			3.30	-0.10
Q3			3.60	0.10
Maximum			4.4	1.1

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（113/114）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 40				
N	0	0	90	90
Mean			3.37	-0.04
SD			0.414	0.359
Minimum			2.5	-1.2
Q1			3.00	-0.20
Median			3.40	0.00
Q3			3.70	0.20
Maximum			4.2	0.9
Week 46				
N	0	0	87	87
Mean			3.30	-0.12
SD			0.378	0.346
Minimum			2.3	-1.1
Q1			3.00	-0.40
Median			3.30	-0.20
Q3			3.60	0.10
Maximum			4.0	0.7

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-57　血液生化学検査の評価時点別変化量（OCT-001 試験）（114/114）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	P -> 1 mg (N=95) Observed Value at Visit	P -> 1 mg (N=95) Change from Baseline	1 mg -> 1 mg (N=117) Observed Value at Visit	1 mg -> 1 mg (N=117) Change from Baseline
Week 52				
N	0	0	87	87
Mean			3.36	-0.06
SD			0.446	0.375
Minimum			2.3	-1.2
Q1			3.00	-0.30
Median			3.40	-0.10
Q3			3.70	0.20
Maximum			4.3	0.9

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.1

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（1/57）

AST (GOT)

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	86	-	86	-	114	-	114
High	-	3	2	5	-	1	-	1
Total	-	89	2	91	-	115	-	115
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	87	-	87	-	112	-	112
High	-	3	2	5	-	1	-	1
Total	-	90	2	92	-	113	-	113
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	84	1	85	-	107	-	107
High	-	2	1	3	-	-	-	-
Total	-	86	2	88	-	107	-	107
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	80	-	80	-	108	-	108
High	-	3	2	5	-	-	-	-
Total	-	83	2	85	-	108	-	108

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（2/57）

AST (GOT)

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	76	-	76	-	102	-	102
High	-	2	2	4	-	3	-	3
Total	-	78	2	80	-	105	-	105
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	4	-	4	-	101	-	101
High	-	-	-	-	-	1	-	1
Total	-	4	-	4	-	102	-	102
Week 32								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	97	-	97
High	-	-	-	-	-	2	-	2
Total	-	-	-	-	-	99	-	99
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	82	-	82
High	-	-	-	-	-	2	-	2
Total	-	-	-	-	-	84	-	84

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（3/57）

AST (GOT)

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	83	-	83
High	-	-	-	-	-	2	-	2
Total	-	-	-	-	-	85	-	85
Week 52								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	85	-	85
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	-	86	-	86

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（4/57）

ALT (GPT)

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	1	-	1	-	-	-	-
Normal	-	85	-	85	-	115	-	115
High	-	1	4	5	-	1	-	1
Total	-	87	4	91	-	116	-	116
Week 6								
Low	-	1	-	1	-	-	-	-
Normal	-	87	1	88	-	114	-	114
High	-	1	2	3	-	-	-	-
Total	-	89	3	92	-	114	-	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	85	1	86	-	112	-	112
High	-	-	2	2	-	1	-	1
Total	-	85	3	88	-	113	-	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	79	1	80	-	110	-	110
High	-	3	2	5	-	1	-	1
Total	-	82	3	85	-	111	-	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（5/57）

ALT (GPT)

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	76	2	78	-	105	-	105
High	-	1	1	2	-	4	-	4
Total	-	77	3	80	-	109	-	109
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	4	-	4	-	102	-	102
High	-	-	-	-	-	1	-	1
Total	-	4	-	4	-	103	-	103
Week 32								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	98	-	98
High	-	-	-	-	-	3	-	3
Total	-	-	-	-	-	101	-	101
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	86	-	86
High	-	-	-	-	-	4	-	4
Total	-	-	-	-	-	90	-	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（6/57）

ALT (GPT)

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	84	-	84
High	-	-	-	-	-	3	-	3
Total	-	-	-	-	-	87	-	87
Week 52								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	85	-	85
High	-	-	-	-	-	2	-	2
Total	-	-	-	-	-	87	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（7/57）

GGT

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	79	-	79	-	102	3	105
High	-	1	11	12	-	2	9	11
Total	-	80	11	91	-	104	12	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	80	-	80	-	102	4	106
High	-	2	10	12	-	1	7	8
Total	-	82	10	92	-	103	11	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	77	-	77	-	99	3	102
High	-	1	10	11	-	3	8	11
Total	-	78	10	88	-	102	11	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	72	2	74	-	99	4	103
High	-	3	8	11	-	1	7	8
Total	-	75	10	85	-	100	11	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（8/57）

GGT

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	69	3	72	-	95	5	100
High	-	1	7	8	-	3	6	9
Total	-	70	10	80	-	98	11	109
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	3	-	3	-	89	5	94
High	-	1	-	1	-	4	5	9
Total	-	4	-	4	-	93	10	103
Week 32								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	88	5	93
High	-	-	-	-	-	3	5	8
Total	-	-	-	-	-	91	10	101
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	81	4	85
High	-	-	-	-	-	1	4	5
Total	-	-	-	-	-	82	8	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（9/57）

GGT

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	77	5	82
High	-	-	-	-	-	2	3	5
Total	-	-	-	-	-	79	8	87
Week 52								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	78	4	82
High	-	-	-	-	-	1	4	5
Total	-	-	-	-	-	79	8	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（10/57）

Alkaline Phosphatase

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	3	-	-	3
Normal	-	88	-	88	-	106	3	109
High	-	-	3	3	-	1	3	4
Total	-	88	3	91	3	107	6	116
Week 6								
Low	-	-	-	-	2	-	-	2
Normal	-	88	-	88	-	104	2	106
High	-	2	2	4	-	2	4	6
Total	-	90	2	92	2	106	6	114
Week 14								
Low	-	-	-	-	2	-	-	2
Normal	-	84	-	84	-	102	2	104
High	-	2	2	4	-	3	4	7
Total	-	86	2	88	2	105	6	113
Week 20								
Low	-	-	-	-	2	-	-	2
Normal	-	80	-	80	-	100	3	103
High	-	3	2	5	-	3	3	6
Total	-	83	2	85	2	103	6	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（11/57）

Alkaline Phosphatase

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	2	1	-	3
Normal	-	73	-	73	-	97	3	100
High	-	5	2	7	-	3	3	6
Total	-	78	2	80	2	101	6	109
Week 29								
Low	-	-	-	-	1	1	-	2
Normal	-	4	-	4	-	92	2	94
High	-	-	-	-	-	3	4	7
Total	-	4	-	4	1	96	6	103
Week 32								
Low	-	-	-	-	1	1	-	2
Normal	-	-	-	-	-	92	2	94
High	-	-	-	-	-	1	4	5
Total	-	-	-	-	1	94	6	101
Week 40								
Low	-	-	-	-	1	1	-	2
Normal	-	-	-	-	-	78	2	80
High	-	-	-	-	-	6	2	8
Total	-	-	-	-	1	85	4	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（12/57）

Alkaline Phosphatase

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	80	3	83
High	-	-	-	-	-	2	1	3
Total	-	-	-	-	1	82	4	87
Week 52								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	80	2	82
High	-	-	-	-	-	2	2	4
Total	-	-	-	-	1	82	4	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（13/57）

LDH

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	1	-	-	1
Normal	-	87	-	87	1	108	1	110
High	-	-	4	4	-	1	3	4
Total	-	87	4	91	2	109	4	115
Week 6								
Low	-	-	-	-	1	1	-	2
Normal	-	88	2	90	1	104	1	106
High	-	-	2	2	-	2	3	5
Total	-	88	4	92	2	107	4	113
Week 14								
Low	-	-	-	-	1	1	-	2
Normal	-	83	1	84	1	99	1	101
High	-	1	3	4	-	1	3	4
Total	-	84	4	88	2	101	4	107
Week 20								
Low	-	1	-	1	-	1	-	1
Normal	-	79	-	79	2	97	1	100
High	-	1	4	5	-	4	3	7
Total	-	81	4	85	2	102	4	108

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（14/57）

LDH

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	1	1	-	2
Normal	-	75	-	75	1	97	1	99
High	-	1	4	5	-	1	3	4
Total	-	76	4	80	2	99	4	105
Week 29								
Low	-	-	-	-	1	-	-	1
Normal	-	4	-	4	1	93	1	95
High	-	-	-	-	-	3	3	6
Total	-	4	-	4	2	96	4	102
Week 32								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	1	92	-	93
High	-	-	-	-	-	1	4	5
Total	-	-	-	-	2	93	4	99
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	2	76	-	78
High	-	-	-	-	-	2	4	6
Total	-	-	-	-	2	78	4	84

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（15/57）

LDH

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	2	78	1	81
High	-	-	-	-	-	1	3	4
Total	-	-	-	-	2	79	4	85
Week 52								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	1	77	1	79
High	-	-	-	-	-	3	3	6
Total	-	-	-	-	2	80	4	86

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（16/57）

Albumin

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	1	-	-	1	-	-	-	-
Normal	-	90	-	90	1	115	-	116
High	-	-	-	-	-	-	-	-
Total	1	90	-	91	1	115	-	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	1	91	-	92	1	113	-	114
High	-	-	-	-	-	-	-	-
Total	1	91	-	92	1	113	-	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	1	87	-	88	1	112	-	113
High	-	-	-	-	-	-	-	-
Total	1	87	-	88	1	112	-	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	1	84	-	85	1	110	-	111
High	-	-	-	-	-	-	-	-
Total	1	84	-	85	1	110	-	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（17/57）

Albumin

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	1	-	1	-	1	-	1
Normal	1	78	-	79	-	108	-	108
High	-	-	-	-	-	-	-	-
Total	1	79	-	80	-	109	-	109
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	4	-	4	1	102	-	103
High	-	-	-	-	-	-	-	-
Total	-	4	-	4	1	102	-	103
Week 32								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	1	100	-	101
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	100	-	101
Week 40								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	89	-	89
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	89	-	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（18/57）

Albumin

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	1	86	-	87
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	86	-	87
Week 52								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	86	-	86
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	86	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（19/57）

Total Protein

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	4	5	-	9	6	5	-	11
Normal	4	76	2	82	4	100	-	104
High	-	-	-	-	-	1	-	1
Total	8	81	2	91	10	106	-	116
Week 6								
Low	3	8	-	11	7	11	-	18
Normal	5	74	2	81	3	93	-	96
High	-	-	-	-	-	-	-	-
Total	8	82	2	92	10	104	-	114
Week 14								
Low	4	8	-	12	7	10	-	17
Normal	4	70	1	75	3	93	-	96
High	-	-	1	1	-	-	-	-
Total	8	78	2	88	10	103	-	113
Week 20								
Low	4	5	-	9	4	8	-	12
Normal	4	70	1	75	6	93	-	99
High	-	-	1	1	-	-	-	-
Total	8	75	2	85	10	101	-	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（20/57）

Total Protein

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	3	5	-	8	6	8	-	14
Normal	4	66	1	71	4	91	-	95
High	-	-	1	1	-	-	-	-
Total	7	71	2	80	10	99	-	109
Week 29								
Low	-	1	-	1	6	8	-	14
Normal	-	3	-	3	3	85	-	88
High	-	-	-	-	-	1	-	1
Total	-	4	-	4	9	94	-	103
Week 32								
Low	-	-	-	-	5	10	-	15
Normal	-	-	-	-	3	83	-	86
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	8	93	-	101
Week 40								
Low	-	-	-	-	6	8	-	14
Normal	-	-	-	-	2	74	-	76
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	8	82	-	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（21/57）

Total Protein

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	6	12	-	18
Normal	-	-	-	-	2	66	-	68
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	8	79	-	87
Week 52								
Low	-	-	-	-	3	8	-	11
Normal	-	-	-	-	5	71	-	76
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	8	79	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（22/57）

Total Bilirubin

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	80	2	82	-	100	4	104
High	-	1	8	9	-	6	6	12
Total	-	81	10	91	-	106	10	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	78	2	80	-	100	2	102
High	-	4	8	12	-	4	8	12
Total	-	82	10	92	-	104	10	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	78	3	81	-	101	3	104
High	-	2	5	7	-	2	7	9
Total	-	80	8	88	-	103	10	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	74	2	76	-	96	3	99
High	-	3	6	9	-	5	7	12
Total	-	77	8	85	-	101	10	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（23/57）

Total Bilirubin

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	71	4	75	-	94	3	97
High	-	1	4	5	-	5	7	12
Total	-	72	8	80	-	99	10	109
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	4	-	4	-	91	3	94
High	-	-	-	-	-	3	6	9
Total	-	4	-	4	-	94	9	103
Week 32								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	89	4	93
High	-	-	-	-	-	3	5	8
Total	-	-	-	-	-	92	9	101
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	80	3	83
High	-	-	-	-	-	3	4	7
Total	-	-	-	-	-	83	7	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（24/57）

Total Bilirubin

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	79	2	81
High	-	-	-	-	-	1	5	6
Total	-	-	-	-	-	80	7	87
Week 52								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	75	3	78
High	-	-	-	-	-	5	4	9
Total	-	-	-	-	-	80	7	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（25/57）

Total Cholesterol

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	1	-	-	1
Normal	-	58	8	66	-	71	10	81
High	-	4	21	25	-	5	29	34
Total	-	62	29	91	1	76	39	116
Week 6								
Low	-	-	-	-	1	-	-	1
Normal	-	59	7	66	-	69	15	84
High	-	4	22	26	-	5	24	29
Total	-	63	29	92	1	74	39	114
Week 14								
Low	-	-	-	-	1	-	-	1
Normal	-	54	10	64	-	65	15	80
High	-	5	19	24	-	9	23	32
Total	-	59	29	88	1	74	38	113
Week 20								
Low	-	-	-	-	1	-	-	1
Normal	-	52	9	61	-	69	17	86
High	-	4	20	24	-	3	21	24
Total	-	56	29	85	1	72	38	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（26/57）

Total Cholesterol

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	1	-	-	1
Normal	-	47	9	56	-	64	12	76
High	-	6	18	24	-	7	25	32
Total	-	53	27	80	1	71	37	109
Week 29								
Low	-	-	-	-	1	-	-	1
Normal	-	2	1	3	-	59	15	74
High	-	-	1	1	-	7	21	28
Total	-	2	2	4	1	66	36	103
Week 32								
Low	-	-	-	-	1	1	-	2
Normal	-	-	-	-	-	59	13	72
High	-	-	-	-	-	6	21	27
Total	-	-	-	-	1	66	34	101
Week 40								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	54	11	65
High	-	-	-	-	-	7	17	24
Total	-	-	-	-	1	61	28	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（27/57）

Total Cholesterol

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	53	10	63
High	-	-	-	-	-	5	18	23
Total	-	-	-	-	1	58	28	87
Week 52								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	55	13	68
High	-	-	-	-	-	3	15	18
Total	-	-	-	-	1	58	28	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（28/57）

Triglycerides

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	75	4	79	-	95	5	100
High	-	8	4	12	-	5	11	16
Total	-	83	8	91	-	100	16	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	80	3	83	-	94	8	102
High	-	5	4	9	-	5	7	12
Total	-	85	7	92	-	99	15	114
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	-	76	3	79	-	95	6	101
High	-	5	4	9	-	3	9	12
Total	-	81	7	88	-	98	15	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	73	5	78	-	92	7	99
High	-	5	2	7	-	4	8	12
Total	-	78	7	85	-	96	15	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（29/57）

Triglycerides

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	-	-	-
Normal	-	68	2	70	-	90	5	95
High	-	5	5	10	-	4	10	14
Total	-	73	7	80	-	94	15	109
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	4	-	4	-	83	6	89
High	-	-	-	-	-	6	8	14
Total	-	4	-	4	-	89	14	103
Week 32								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	79	8	87
High	-	-	-	-	-	8	6	14
Total	-	-	-	-	-	87	14	101
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	72	6	78
High	-	-	-	-	-	5	7	12
Total	-	-	-	-	-	77	13	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（30/57）

Triglycerides

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	69	5	74
High	-	-	-	-	-	5	8	13
Total	-	-	-	-	-	74	13	87
Week 52								
Low	-	-	-	-	-	1	-	1
Normal	-	-	-	-	-	69	6	75
High	-	-	-	-	-	4	7	11
Total	-	-	-	-	-	74	13	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（31/57）

Creatinine

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	1	1	-	2	1	1	-	2
Normal	3	77	3	83	1	101	4	106
High	-	-	6	6	-	1	7	8
Total	4	78	9	91	2	103	11	116
Week 6								
Low	2	1	-	3	1	-	-	1
Normal	2	79	4	85	1	100	1	102
High	-	-	4	4	-	1	10	11
Total	4	80	8	92	2	101	11	114
Week 14								
Low	1	-	-	1	2	1	-	3
Normal	3	75	5	83	-	98	1	99
High	-	2	2	4	-	1	10	11
Total	4	77	7	88	2	100	11	113
Week 20								
Low	-	3	-	3	1	1	-	2
Normal	3	70	5	78	1	92	1	94
High	-	2	2	4	-	5	10	15
Total	3	75	7	85	2	98	11	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（32/57）

Creatinine

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	1	1	-	2
Normal	2	69	4	75	1	90	4	95
High	-	2	3	5	-	5	7	12
Total	2	71	7	80	2	96	11	109
Week 29								
Low	-	-	-	-	1	2	-	3
Normal	-	4	-	4	1	86	4	91
High	-	-	-	-	-	3	6	9
Total	-	4	-	4	2	91	10	103
Week 32								
Low	-	-	-	-	1	1	-	2
Normal	-	-	-	-	1	86	3	90
High	-	-	-	-	-	2	7	9
Total	-	-	-	-	2	89	10	101
Week 40								
Low	-	-	-	-	-	1	-	1
Normal	-	-	-	-	1	79	3	83
High	-	-	-	-	-	-	6	6
Total	-	-	-	-	1	80	9	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（33/57）

Creatinine

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	1	77	3	81
High	-	-	-	-	-	-	6	6
Total	-	-	-	-	1	77	9	87
Week 52								
Low	-	-	-	-	1	3	-	4
Normal	-	-	-	-	-	72	2	74
High	-	-	-	-	-	2	7	9
Total	-	-	-	-	1	77	9	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（34/57）

Blood Urea Nitrogen

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	-	-	-
Normal	-	88	1	89	1	109	2	112
High	-	2	-	2	-	3	1	4
Total	-	90	1	91	1	112	3	116
Week 6								
Low	-	-	-	-	-	-	-	-
Normal	-	89	1	90	1	109	-	110
High	-	2	-	2	-	1	3	4
Total	-	91	1	92	1	110	3	114
Week 14								
Low	-	-	-	-	-	1	-	1
Normal	-	85	1	86	1	108	1	110
High	-	2	-	2	-	-	2	2
Total	-	87	1	88	1	109	3	113
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	83	1	84	1	105	2	108
High	-	1	-	1	-	2	1	3
Total	-	84	1	85	1	107	3	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（35/57）

Blood Urea Nitrogen

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	1	-	-	1
Normal	-	76	1	77	-	102	1	103
High	-	3	-	3	-	3	2	5
Total	-	79	1	80	1	105	3	109
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	4	-	4	1	97	2	100
High	-	-	-	-	-	2	1	3
Total	-	4	-	4	1	99	3	103
Week 32								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	1	96	1	98
High	-	-	-	-	-	1	2	3
Total	-	-	-	-	1	97	3	101
Week 40								
Low	-	-	-	-	-	2	-	2
Normal	-	-	-	-	-	83	1	84
High	-	-	-	-	-	2	2	4
Total	-	-	-	-	-	87	3	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（36/57）

Blood Urea Nitrogen

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	81	1	82
High	-	-	-	-	-	3	2	5
Total	-	-	-	-	-	84	3	87
Week 52								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	81	1	82
High	-	-	-	-	-	3	2	5
Total	-	-	-	-	-	84	3	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（37/57）

Uric Acid

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	3	-	-	3	4	1	-	5
Normal	1	83	2	86	2	103	4	109
High	-	-	2	2	-	1	1	2
Total	4	83	4	91	6	105	5	116
Week 6								
Low	2	-	-	2	2	-	-	2
Normal	2	83	2	87	4	102	3	109
High	-	1	2	3	-	1	2	3
Total	4	84	4	92	6	103	5	114
Week 14								
Low	3	4	-	7	4	-	-	4
Normal	1	73	2	76	2	100	4	106
High	-	3	2	5	-	2	1	3
Total	4	80	4	88	6	102	5	113
Week 20								
Low	1	2	-	3	4	-	-	4
Normal	2	74	2	78	2	97	5	104
High	-	2	2	4	-	3	-	3
Total	3	78	4	85	6	100	5	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（38/57）

Uric Acid

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	2	3	-	5	4	1	-	5
Normal	1	71	-	72	2	97	2	101
High	-	-	3	3	-	-	3	3
Total	3	74	3	80	6	98	5	109
Week 29								
Low	-	-	-	-	4	-	-	4
Normal	-	3	-	3	2	91	2	95
High	-	-	1	1	-	1	3	4
Total	-	3	1	4	6	92	5	103
Week 32								
Low	-	-	-	-	3	-	-	3
Normal	-	-	-	-	2	90	4	96
High	-	-	-	-	-	1	1	2
Total	-	-	-	-	5	91	5	101
Week 40								
Low	-	-	-	-	3	1	-	4
Normal	-	-	-	-	1	81	1	83
High	-	-	-	-	-	-	3	3
Total	-	-	-	-	4	82	4	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（39/57）

Uric Acid

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	3	1	-	4
Normal	-	-	-	-	1	78	3	82
High	-	-	-	-	-	-	1	1
Total	-	-	-	-	4	79	4	87
Week 52								
Low	-	-	-	-	3	-	-	3
Normal	-	-	-	-	1	77	3	81
High	-	-	-	-	-	2	1	3
Total	-	-	-	-	4	79	4	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（40/57）

CK (CPK)

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	3	2	-	5	7	2	-	9
Normal	1	77	3	81	2	91	4	97
High	-	1	4	5	-	3	7	10
Total	4	80	7	91	9	96	11	116
Week 6								
Low	3	2	-	5	7	2	-	9
Normal	1	77	4	82	2	85	4	91
High	-	2	3	5	-	7	7	14
Total	4	81	7	92	9	94	11	114
Week 14								
Low	3	3	-	6	7	4	-	11
Normal	-	71	2	73	2	84	5	91
High	-	4	5	9	-	5	6	11
Total	3	78	7	88	9	93	11	113
Week 20								
Low	2	3	-	5	4	1	-	5
Normal	1	68	3	72	5	86	4	95
High	-	4	4	8	-	5	6	11
Total	3	75	7	85	9	92	10	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（41/57）

CK (CPK)

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	3	4	-	7	6	3	-	9
Normal	-	66	3	69	2	82	7	91
High	-	-	4	4	-	6	3	9
Total	3	70	7	80	8	91	10	109
Week 29								
Low	-	-	-	-	5	3	-	8
Normal	-	4	-	4	3	75	3	81
High	-	-	-	-	-	7	7	14
Total	-	4	-	4	8	85	10	103
Week 32								
Low	-	-	-	-	6	-	-	6
Normal	-	-	-	-	1	80	3	84
High	-	-	-	-	1	3	7	11
Total	-	-	-	-	8	83	10	101
Week 40								
Low	-	-	-	-	4	2	-	6
Normal	-	-	-	-	3	66	5	74
High	-	-	-	-	-	5	5	10
Total	-	-	-	-	7	73	10	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（42/57）

CK (CPK)

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	4	3	-	7
Normal	-	-	-	-	3	62	4	69
High	-	-	-	-	-	6	5	11
Total	-	-	-	-	7	71	9	87
Week 52								
Low	-	-	-	-	4	1	-	5
Normal	-	-	-	-	3	64	3	70
High	-	-	-	-	-	6	6	12
Total	-	-	-	-	7	71	9	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（43/57）

Sodium

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	3	-	3	1	1	-	2
Normal	1	87	-	88	1	113	-	114
High	-	-	-	-	-	-	-	-
Total	1	90	-	91	2	114	-	116
Week 6								
Low	-	1	-	1	1	-	-	1
Normal	1	90	-	91	1	112	-	113
High	-	-	-	-	-	-	-	-
Total	1	91	-	92	2	112	-	114
Week 14								
Low	-	3	-	3	2	1	-	3
Normal	1	84	-	85	-	109	-	109
High	-	-	-	-	-	1	-	1
Total	1	87	-	88	2	111	-	113
Week 20								
Low	1	2	-	3	1	1	-	2
Normal	-	82	-	82	1	108	-	109
High	-	-	-	-	-	-	-	-
Total	1	84	-	85	2	109	-	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（44/57）

Sodium

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	4	-	4	2	1	-	3
Normal	1	75	-	76	-	106	-	106
High	-	-	-	-	-	-	-	-
Total	1	79	-	80	2	107	-	109
Week 29								
Low	-	-	-	-	2	-	-	2
Normal	-	4	-	4	-	101	-	101
High	-	-	-	-	-	-	-	-
Total	-	4	-	4	2	101	-	103
Week 32								
Low	-	-	-	-	2	3	-	5
Normal	-	-	-	-	-	96	-	96
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	2	99	-	101
Week 40								
Low	-	-	-	-	1	1	-	2
Normal	-	-	-	-	-	88	-	88
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	89	-	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（45/57）

Sodium

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	1	2	-	3
Normal	-	-	-	-	-	84	-	84
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	86	-	87
Week 52								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	86	-	86
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	86	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（46/57）

Potassium

Visit	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	1	-	-	1
Normal	1	88	2	91	-	114	-	114
High	-	-	-	-	-	-	-	-
Total	1	88	2	91	1	114	-	115
Week 6								
Low	-	1	-	1	1	-	-	1
Normal	1	86	2	89	-	111	-	111
High	-	2	-	2	-	1	-	1
Total	1	89	2	92	1	112	-	113
Week 14								
Low	-	-	-	-	-	-	-	-
Normal	1	84	1	86	1	105	-	106
High	-	1	1	2	-	1	-	1
Total	1	85	2	88	1	106	-	107
Week 20								
Low	-	1	-	1	-	-	-	-
Normal	1	81	2	84	1	106	-	107
High	-	-	-	-	-	1	-	1
Total	1	82	2	85	1	107	-	108

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（47/57）

Potassium

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	1	-	1
Normal	1	77	2	80	1	102	-	103
High	-	-	-	-	-	1	-	1
Total	1	77	2	80	1	104	-	105
Week 29								
Low	-	-	-	-	-	1	-	1
Normal	-	4	-	4	1	99	-	100
High	-	-	-	-	-	1	-	1
Total	-	4	-	4	1	101	-	102
Week 32								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	97	-	97
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	1	98	-	99
Week 40								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	83	-	83
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	83	-	84

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（48/57）

Potassium

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	1	84	-	85
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	84	-	85
Week 52								
Low	-	-	-	-	1	-	-	1
Normal	-	-	-	-	-	85	-	85
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	85	-	86

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（49/57）

Chloride

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	1	-	1	-	1	-	1
Normal	1	87	2	90	1	113	1	115
High	-	-	-	-	-	-	-	-
Total	1	88	2	91	1	114	1	116
Week 6								
Low	1	1	-	2	-	-	-	-
Normal	-	88	2	90	1	112	1	114
High	-	-	-	-	-	-	-	-
Total	1	89	2	92	1	112	1	114
Week 14								
Low	-	1	-	1	1	-	-	1
Normal	1	84	2	87	-	111	1	112
High	-	-	-	-	-	-	-	-
Total	1	85	2	88	1	111	1	113
Week 20								
Low	-	3	-	3	1	1	-	2
Normal	1	79	2	82	-	108	1	109
High	-	-	-	-	-	-	-	-
Total	1	82	2	85	1	109	1	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（50/57）

Chloride

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	3	-	3	-	-	-	-
Normal	1	74	2	77	1	107	1	109
High	-	-	-	-	-	-	-	-
Total	1	77	2	80	1	107	1	109
Week 29								
Low	-	-	-	-	1	1	-	2
Normal	-	4	-	4	-	100	1	101
High	-	-	-	-	-	-	-	-
Total	-	4	-	4	1	101	1	103
Week 32								
Low	-	-	-	-	1	1	-	2
Normal	-	-	-	-	-	98	1	99
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	99	1	101
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	-	89	1	90
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	89	1	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（51/57）

Chloride

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	1	-	1
Normal	-	-	-	-	-	84	1	85
High	-	-	-	-	-	1	-	1
Total	-	-	-	-	-	86	1	87
Week 52								
Low	-	-	-	-	-	1	-	1
Normal	-	-	-	-	-	85	1	86
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	86	1	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（52/57）

Calcium

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	-	-	-	-	-	1	-	1
Normal	-	91	-	91	-	115	-	115
High	-	-	-	-	-	-	-	-
Total	-	91	-	91	-	116	-	116
Week 6								
Low	-	-	-	-	-	1	-	1
Normal	-	92	-	92	-	113	-	113
High	-	-	-	-	-	-	-	-
Total	-	92	-	92	-	114	-	114
Week 14								
Low	-	-	-	-	-	1	-	1
Normal	-	88	-	88	-	112	-	112
High	-	-	-	-	-	-	-	-
Total	-	88	-	88	-	113	-	113
Week 20								
Low	-	1	-	1	-	-	-	-
Normal	-	84	-	84	-	111	-	111
High	-	-	-	-	-	-	-	-
Total	-	85	-	85	-	111	-	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（53/57）

Calcium

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	1	-	1	-	1	-	1
Normal	-	79	-	79	-	108	-	108
High	-	-	-	-	-	-	-	-
Total	-	80	-	80	-	109	-	109
Week 29								
Low	-	-	-	-	-	-	-	-
Normal	-	4	-	4	-	103	-	103
High	-	-	-	-	-	-	-	-
Total	-	4	-	4	-	103	-	103
Week 32								
Low	-	-	-	-	-	1	-	1
Normal	-	-	-	-	-	100	-	100
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	101	-	101
Week 40								
Low	-	-	-	-	-	2	-	2
Normal	-	-	-	-	-	88	-	88
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	90	-	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（54/57）

Calcium

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	1	-	1
Normal	-	-	-	-	-	86	-	86
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	87	-	87
Week 52								
Low	-	-	-	-	-	3	-	3
Normal	-	-	-	-	-	84	-	84
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	87	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（55/57）

Phosphorus

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 3								
Low	1	-	-	1	-	1	-	1
Normal	1	89	-	90	1	114	-	115
High	-	-	-	-	-	-	-	-
Total	2	89	-	91	1	115	-	116
Week 6								
Low	1	2	-	3	-	-	-	-
Normal	1	88	-	89	1	113	-	114
High	-	-	-	-	-	-	-	-
Total	2	90	-	92	1	113	-	114
Week 14								
Low	1	2	-	3	-	1	-	1
Normal	1	84	-	85	1	111	-	112
High	-	-	-	-	-	-	-	-
Total	2	86	-	88	1	112	-	113
Week 20								
Low	-	-	-	-	-	1	-	1
Normal	2	83	-	85	1	108	-	109
High	-	-	-	-	-	1	-	1
Total	2	83	-	85	1	110	-	111

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（56/57）

Phosphorus

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 26								
Low	-	-	-	-	-	1	-	1
Normal	2	78	-	80	1	106	-	107
High	-	-	-	-	-	1	-	1
Total	2	78	-	80	1	108	-	109
Week 29								
Low	-	-	-	-	-	2	-	2
Normal	-	4	-	4	1	100	-	101
High	-	-	-	-	-	-	-	-
Total	-	4	-	4	1	102	-	103
Week 32								
Low	-	-	-	-	-	2	-	2
Normal	-	-	-	-	1	98	-	99
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	100	-	101
Week 40								
Low	-	-	-	-	-	-	-	-
Normal	-	-	-	-	1	89	-	90
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	89	-	90

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-58　血液生化学検査の正異判定のクロス表（OCT-001 試験）（57/57）

Phosphorus

	Baseline							
	P -> 1 mg (N=95)				1 mg -> 1 mg (N=117)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 46								
Low	-	-	-	-	-	1	-	1
Normal	-	-	-	-	1	85	-	86
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	86	-	87
Week 52								
Low	-	-	-	-	-	1	-	1
Normal	-	-	-	-	1	85	-	86
High	-	-	-	-	-	-	-	-
Total	-	-	-	-	1	86	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.1.3

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（1/16）

Protein

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 3														
-	89	1	-	-	-	-	90	100	5	-	1	-	-	106
+-	-	-	-	-	-	-	-	4	-	1	-	-	-	5
1+	1	-	-	-	-	-	1	-	1	1	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	2	-	-	2
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	90	1	-	-	-	-	91	104	6	2	3	1	-	116
Week 6														
-	86	1	-	-	-	-	87	100	2	-	1	-	-	103
+-	3	-	-	-	-	-	3	4	2	-	-	-	-	6
1+	2	-	-	-	-	-	2	-	2	1	-	-	-	3
2+	-	-	-	-	-	-	-	-	-	-	1	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	91	1	-	-	-	-	92	104	6	1	2	1	-	114
Week 14														
-	85	1	-	-	-	-	86	101	5	-	1	-	-	107
+-	2	-	-	-	-	-	2	1	1	-	1	-	-	3
1+	-	-	-	-	-	-	-	1	-	1	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	87	1	-	-	-	-	88	103	6	1	2	1	-	113

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（2/16）

Protein

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 20														
-	78	1	-	-	-	-	79	95	4	-	1	-	-	100
+-	4	-	-	-	-	-	4	5	1	-	-	-	-	6
1+	2	-	-	-	-	-	2	-	1	1	-	-	-	2
2+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	1	1	-	2
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	84	1	-	-	-	-	85	101	6	1	2	1	-	111
Week 26														
-	74	1	-	-	-	-	75	96	5	-	-	-	-	101
+-	3	-	-	-	-	-	3	3	-	1	1	-	-	5
1+	1	-	-	-	-	-	1	1	1	-	-	-	-	2
2+	1	-	-	-	-	-	1	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	79	1	-	-	-	-	80	100	6	1	1	1	-	109
Week 29														
-	4	-	-	-	-	-	4	88	4	-	-	-	-	92
+-	-	-	-	-	-	-	-	3	-	-	-	-	-	3
1+	-	-	-	-	-	-	-	3	-	1	1	-	-	5
2+	-	-	-	-	-	-	-	1	1	-	-	-	-	2
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	-	-	-	-	-	4	95	5	1	1	1	-	103

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（3/16）

Protein

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 32														
-	-	-	-	-	-	-	-	89	5	-	1	-	-	95
+-	-	-	-	-	-	-	-	4	-	1	-	-	-	5
1+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	93	5	1	1	1	-	101
Week 40														
-	-	-	-	-	-	-	-	74	4	-	-	-	-	78
+-	-	-	-	-	-	-	-	7	-	-	-	-	-	7
1+	-	-	-	-	-	-	-	-	1	1	1	-	-	3
2+	-	-	-	-	-	-	-	1	-	-	-	1	-	2
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	82	5	1	1	1	-	90
Week 46														
-	-	-	-	-	-	-	-	74	1	-	1	-	-	76
+-	-	-	-	-	-	-	-	3	3	-	-	-	-	6
1+	-	-	-	-	-	-	-	2	1	-	-	-	-	3
2+	-	-	-	-	-	-	-	-	-	1	-	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	79	5	1	1	1	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（4/16）

Protein

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 52														
-	-	-	-	-	-	-	-	74	2	-	1	-	-	77
+-	-	-	-	-	-	-	-	3	3	-	-	-	-	6
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	1	-	1	-	-	-	2
3+	-	-	-	-	-	-	-	-	-	-	-	1	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	79	5	1	1	1	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（5/16）

Glucose

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	1+	2+	3+	4+	5+	Total	-	1+	2+	3+	4+	5+	Total
Week 3														
-	89	1	-	-	-	-	90	115	-	-	-	-	-	115
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	1	-	-	1	-	-	-	-	-	-	-
Total	89	1	-	1	-	-	91	116	-	-	-	-	-	116
Week 6														
-	87	2	-	-	-	-	89	113	-	-	-	-	-	113
1+	1	-	-	-	-	-	1	-	-	-	-	-	-	-
2+	1	-	-	-	-	-	1	1	-	-	-	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	1	-	-	1	-	-	-	-	-	-	-
Total	89	2	-	1	-	-	92	114	-	-	-	-	-	114
Week 14														
-	84	2	-	-	-	-	86	111	-	-	-	-	-	111
1+	1	-	-	-	-	-	1	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	1	-	-	1	-	-	-	-	-	-	-
Total	85	2	-	1	-	-	88	113	-	-	-	-	-	113

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（6/16）

Glucose

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	1+	2+	3+	4+	5+	Total	-	1+	2+	3+	4+	5+	Total
Week 20														
-	82	2	-	-	-	-	84	109	-	-	-	-	-	109
1+	-	-	-	-	-	-	-	2	-	-	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	1	-	-	1	-	-	-	-	-	-	-
Total	82	2	-	1	-	-	85	111	-	-	-	-	-	111
Week 26														
-	75	1	-	-	-	-	76	107	-	-	-	-	-	107
1+	1	1	-	-	-	-	2	-	-	-	-	-	-	-
2+	1	-	-	-	-	-	1	2	-	-	-	-	-	2
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	1	-	-	1	-	-	-	-	-	-	-
Total	77	2	-	1	-	-	80	109	-	-	-	-	-	109
Week 29														
-	4	-	-	-	-	-	4	102	-	-	-	-	-	102
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	-	-	-	-	-	4	103	-	-	-	-	-	103

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（7/16）

Glucose

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	1+	2+	3+	4+	5+	Total	-	1+	2+	3+	4+	5+	Total
Week 32														
-	-	-	-	-	-	-	-	101	-	-	-	-	-	101
1+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	101	-	-	-	-	-	101
Week 40														
-	-	-	-	-	-	-	-	88	-	-	-	-	-	88
1+	-	-	-	-	-	-	-	2	-	-	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	90	-	-	-	-	-	90
Week 46														
-	-	-	-	-	-	-	-	85	-	-	-	-	-	85
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
Total	-	-	-	-	-	-	-	87	-	-	-	-	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（8/16）

Glucose

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	1+	2+	3+	4+	5+	Total	-	1+	2+	3+	4+	5+	Total
Week 52														
-	-	-	-	-	-	-	-	85	-	-	-	-	-	85
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
5+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	87	-	-	-	-	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（9/16）

Occult Blood

	Baseline											
	P -> 1 mg (N=95)						1 mg -> 1 mg (N=117)					
Visit	-	+-	1+	2+	3+	Total	-	+-	1+	2+	3+	Total
Week 3												
-	73	2	2	-	-	77	75	9	2	-	-	86
+-	2	3	-	-	-	5	6	1	4	-	-	11
1+	-	2	2	1	-	5	1	1	4	1	1	8
2+	-	-	-	1	-	1	1	-	4	3	-	8
3+	1	-	-	2	-	3	1	-	1	1	-	3
Total	76	7	4	4	-	91	84	11	15	5	1	116
Week 6												
-	71	2	1	-	-	74	76	6	2	-	-	84
+-	1	3	-	-	-	4	7	4	2	-	-	13
1+	1	3	3	2	-	9	-	-	4	3	-	7
2+	-	-	1	2	-	3	-	-	7	1	-	8
3+	1	-	-	1	-	2	-	1	-	1	-	2
Total	74	8	5	5	-	92	83	11	15	5	-	114
Week 14												
-	64	2	1	-	-	67	79	5	5	-	-	89
+-	1	4	2	1	-	8	3	4	5	1	-	13
1+	3	2	1	1	-	7	1	1	3	-	-	5
2+	1	-	1	1	-	3	-	-	-	3	-	3
3+	1	-	-	2	-	3	-	1	1	1	-	3
Total	70	8	5	5	-	88	83	11	14	5	-	113

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（10/16）

Occult Blood

	Baseline											
	P -> 1 mg (N=95)						1 mg -> 1 mg (N=117)					
Visit	-	+-	1+	2+	3+	Total	-	+-	1+	2+	3+	Total
Week 20												
-	65	1	1	-	-	67	78	5	4	-	-	87
+-	-	3	2	-	-	5	5	3	2	1	-	11
1+	2	2	1	2	-	7	-	3	5	1	-	9
2+	1	-	1	1	-	3	-	-	1	2	-	3
3+	-	1	-	2	-	3	-	-	-	1	-	1
Total	68	7	5	5	-	85	83	11	12	5	-	111
Week 26												
-	60	2	-	-	-	62	77	6	4	-	-	87
+-	5	3	2	-	-	10	2	1	4	-	-	7
1+	1	-	-	1	-	2	4	2	2	1	-	9
2+	1	1	1	-	-	3	-	-	2	4	-	6
3+	-	1	-	2	-	3	-	-	-	-	-	-
Total	67	7	3	3	-	80	83	9	12	5	-	109
Week 29												
-	-	-	-	-	-	-	69	5	3	-	-	77
+-	1	-	-	-	-	1	2	3	3	1	-	9
1+	-	-	-	-	-	-	6	1	3	1	-	11
2+	-	-	1	2	-	3	-	1	2	2	-	5
3+	-	-	-	-	-	-	-	-	-	1	-	1
Total	1	-	1	2	-	4	77	10	11	5	-	103

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（11/16）

Occult Blood

	Baseline											
	P -> 1 mg (N=95)						1 mg -> 1 mg (N=117)					
Visit	-	+-	1+	2+	3+	Total	-	+-	1+	2+	3+	Total
Week 32												
-	-	-	-	-	-	-	70	6	4	1	-	81
+-	-	-	-	-	-	-	3	-	3	-	-	6
1+	-	-	-	-	-	-	3	4	2	1	-	10
2+	-	-	-	-	-	-	-	-	2	1	-	3
3+	-	-	-	-	-	-	-	-	-	1	-	1
Total	-	-	-	-	-	-	76	10	11	4	-	101
Week 40												
-	-	-	-	-	-	-	63	5	3	-	-	71
+-	-	-	-	-	-	-	3	1	-	-	-	4
1+	-	-	-	-	-	-	3	3	4	2	-	12
2+	-	-	-	-	-	-	-	1	1	-	-	2
3+	-	-	-	-	-	-	-	-	-	1	-	1
Total	-	-	-	-	-	-	69	10	8	3	-	90
Week 46												
-	-	-	-	-	-	-	65	7	2	-	-	74
+-	-	-	-	-	-	-	2	1	2	-	-	5
1+	-	-	-	-	-	-	1	-	2	2	-	5
2+	-	-	-	-	-	-	-	-	1	1	-	2
3+	-	-	-	-	-	-	-	1	-	-	-	1
Total	-	-	-	-	-	-	68	9	7	3	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（12/16）

Occult Blood

	Baseline											
	P -> 1 mg (N=95)						1 mg -> 1 mg (N=117)					
Visit	-	+-	1+	2+	3+	Total	-	+-	1+	2+	3+	Total
Week 52												
-	-	-	-	-	-	-	64	6	3	-	-	73
+-	-	-	-	-	-	-	2	1	3	1	-	7
1+	-	-	-	-	-	-	1	1	1	-	-	3
2+	-	-	-	-	-	-	1	1	-	2	-	4
3+	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	68	9	7	3	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（13/16）

Ketones

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 3														
-	85	1	1	-	-	-	87	107	2	1	-	-	-	110
+-	2	-	-	-	-	-	2	4	-	-	-	-	-	4
1+	1	1	-	-	-	-	2	2	-	-	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	88	2	1	-	-	-	91	113	2	1	-	-	-	116
Week 6														
-	88	1	1	-	-	-	90	109	2	-	-	-	-	111
+-	1	-	-	-	-	-	1	1	-	1	-	-	-	2
1+	-	1	-	-	-	-	1	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	89	2	1	-	-	-	92	111	2	1	-	-	-	114
Week 14														
-	84	-	1	-	-	-	85	109	2	-	-	-	-	111
+-	1	2	-	-	-	-	3	1	-	1	-	-	-	2
1+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	85	2	1	-	-	-	88	110	2	1	-	-	-	113

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（14/16）

Ketones

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 20														
-	78	1	1	-	-	-	80	106	2	-	-	-	-	108
+-	3	1	-	-	-	-	4	1	-	1	-	-	-	2
1+	1	-	-	-	-	-	1	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	82	2	1	-	-	-	85	108	2	1	-	-	-	111
Week 26														
-	76	1	1	-	-	-	78	104	2	1	-	-	-	107
+-	1	-	-	-	-	-	1	1	-	-	-	-	-	1
1+	-	1	-	-	-	-	1	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	77	2	1	-	-	-	80	106	2	1	-	-	-	109
Week 29														
-	4	-	-	-	-	-	4	99	2	1	-	-	-	102
+-	-	-	-	-	-	-	-	1	-	-	-	-	-	1
1+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	-	-	-	-	-	4	100	2	1	-	-	-	103

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（15/16）

Ketones

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 32														
-	-	-	-	-	-	-	-	95	2	1	-	-	-	98
+-	-	-	-	-	-	-	-	3	-	-	-	-	-	3
1+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	98	2	1	-	-	-	101
Week 40														
-	-	-	-	-	-	-	-	85	2	1	-	-	-	88
+-	-	-	-	-	-	-	-	2	-	-	-	-	-	2
1+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	87	2	1	-	-	-	90
Week 46														
-	-	-	-	-	-	-	-	82	2	1	-	-	-	85
+-	-	-	-	-	-	-	-	1	-	-	-	-	-	1
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	84	2	1	-	-	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-59　尿検査の正異判定のクロス表（OCT-001 試験）（16/16）

Ketones

	Baseline													
	P -> 1 mg (N=95)							1 mg -> 1 mg (N=117)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 52														
-	-	-	-	-	-	-	-	82	2	1	-	-	-	85
+-	-	-	-	-	-	-	-	1	-	-	-	-	-	1
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	-	-	-	-	-	-	84	2	1	-	-	-	87

Statistical Analysis Report (5.3.5.2-4) Table 3.2.1.2

表 2.7.4.7-付録-60　血液学的検査の変化量（232 試験）（1/2）

Protocol:TVP-1012/232 Placebo-Controlled Phase		1 mg			2 mg			PLACEBO		
		N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*
Parameter (unit)										
BASOPHILS (%)	Baseline	134	0.70	0.00	132	0.73	0.00	138	0.73	0.00
	week 14	117	0.73	0.04	114	0.75	-0.00	119	0.73	-0.02
	Termination	129	0.73	0.03	131	0.77	0.03	134	0.79	0.07
EOSINOPHILS (%)	Baseline	134	2.04	0.00	132	1.83	0.00	138	1.72	0.00
	week 14	117	1.99	0.01	114	1.93	0.09	119	1.86	0.16
	Termination	129	1.91	-0.10	131	1.91	0.08	134	1.93	0.19
HEMATOCRIT (%)	Baseline	134	42.26	0.00	132	41.60	0.00	138	42.27	0.00
	week 14	116	42.41	0.32	114	42.20	0.49	119	42.33	0.13
	Termination	129	42.31	0.05	131	41.49	-0.15	134	42.68	0.34
HEMOGLOBIN (g/dL)	Baseline	134	14.28	0.00	132	14.17	0.00	138	14.35	0.00
	week 14	117	14.12	-0.13	115	14.10	-0.10	119	14.31	-0.03
	Termination	129	14.20	-0.09	131	14.00	-0.18	135	14.37	-0.02
LYMPHOCYTES (%)	Baseline	134	28.46	0.00	132	28.73	0.00	138	28.20	0.00
	week 14	117	28.89	-0.04	114	29.41	0.22	119	28.50	0.26
	Termination	129	28.57	0.17	131	29.21	0.36	134	28.84	0.59
MCH (pg)	Baseline	134	30.90	0.00	132	30.61	0.00	138	30.69	0.00
	week 14	117	30.60	-0.31	115	30.43	-0.13	119	30.67	-0.09
	Termination	129	30.71	-0.21	131	30.52	-0.08	135	30.63	-0.08
MCHC (g/dL)	Baseline	134	33.85	0.00	132	34.15	0.00	138	34.00	0.00
	week 14	116	33.46	-0.46	114	33.53	-0.62	119	33.93	-0.10
	Termination	129	33.66	-0.21	131	33.85	-0.29	134	33.72	-0.31
MCV (fL)	Baseline	134	91.28	0.00	132	89.91	0.00	138	90.17	0.00
	week 14	116	91.58	0.41	114	90.92	1.15	119	90.58	0.22
	Termination	129	91.41	0.15	131	90.40	0.48	134	90.81	0.68
MONOCYTES (%)	Baseline	134	6.74	0.00	132	6.68	0.00	138	6.71	0.00
	week 14	117	6.88	0.17	114	6.73	0.02	119	7.02	0.30
	Termination	129	7.10	0.36	131	6.63	-0.06	134	6.72	-0.02

*BL=Baseline

総括報告書（5.3.5.1-7）Table 61

表 2.7.4.7-付録-60　血液学的検査の変化量（232 試験）（2/2）

Protocol:TVP-1012/232 Placebo-Controlled Phase		1 mg			2 mg			PLACEBO		
		N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*
NEUTROPHIL (%)	Baseline	134	62.04	0.00	132	62.02	0.00	138	62.64	0.00
	week 14	117	61.50	-0.16	114	61.17	-0.33	119	61.84	-0.74
	Termination	129	61.67	-0.46	131	61.49	-0.42	134	61.72	-0.84
PLATELETS (x10^3/uL)	Baseline	134	226.60	0.00	132	231.14	0.00	138	232.12	0.00
	week 14	115	230.48	2.65	114	225.60	-2.96	119	227.86	-3.20
	Termination	127	230.85	2.35	131	229.97	-0.89	135	230.35	-0.36
RED BLOOD CELLS (x10^6/uL)	Baseline	134	4.64	0.00	132	4.64	0.00	138	4.70	0.00
	week 14	117	4.64	0.01	115	4.65	-0.00	119	4.69	0.00
	Termination	129	4.64	0.00	131	4.60	-0.05	135	4.71	-0.00
WHITE BLOOD CELLS (x10^3/uL)	Baseline	134	6.08	0.00	132	6.27	0.00	138	6.37	0.00
	week 14	117	6.02	-0.06	115	5.90	-0.27	119	5.95	-0.34
	Termination	129	5.86	-0.21	131	6.01	-0.24	135	6.08	-0.26

*BL=Baseline

総括報告書（5.3.5.1-7）Table 61

表 2.7.4.7-付録-61　血液学的検査の正異判定のクロス表（232 試験）

TVP-1012/232 Placebo-Controlled Phase	A Shift Analysis from Baseline to Last Observed Value																				
	1 mg							2 mg							PLACEBO						
	All	Change From High /Normal to Low		Change From Low /Normal to High		Other*		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*		All	Change From High /Normal to Low		Change From Low /Normal to High		Other*	
		N	%	N	%	N	%		N	%	N	%	N	%		N	%	N	%	N	%
BASOPHILS	133	.	.	.	.	133	100.0	131	.	.	.	.	131	100.0	138	.	.	2	1.4	136	98.6
EOSINOPHILS	133	.	.	3	2.3	130	97.7	131	.	.	2	1.5	129	98.5	138	.	.	3	2.2	135	97.8
HEMATOCRIT	133	4	3.0	.	.	129	97.0	131	4	3.1	.	.	127	96.9	138	2	1.4	1	0.7	135	97.8
HEMOGLOBIN	133	3	2.3	.	.	130	97.7	131	2	1.5	.	.	129	98.5	138	2	1.4	1	0.7	135	97.8
LYMPHOCYTES	133	2	1.5	2	1.5	129	97.0	131	3	2.3	.	.	128	97.7	138	2	1.4	1	0.7	135	97.8
MCH	133	.	.	1	0.8	132	99.2	131	.	.	.	.	131	100.0	138	.	.	.	.	138	100.0
MCHC	133	3	2.3	.	.	130	97.7	131	.	.	.	.	131	100.0	138	2	1.4	.	.	136	98.6
MCV	133	.	.	4	3.0	129	97.0	131	.	.	1	0.8	130	99.2	138	1	0.7	2	1.4	135	97.8
MONOCYTES	133	2	1.5	10	7.5	121	91.0	131	.	.	2	1.5	129	98.5	138	1	0.7	4	2.9	133	96.4
NEUTROPHIL	133	1	0.8	3	2.3	129	97.0	131	.	.	6	4.6	125	95.4	138	2	1.4	3	2.2	133	96.4
PLATELETS	132	.	.	1	0.8	131	99.2	131	2	1.5	.	.	129	98.5	138	.	.	1	0.7	137	99.3
RED BLOOD CELLS	133	6	4.5	.	.	127	95.5	131	6	4.6	.	.	125	95.4	138	6	4.3	1	0.7	131	94.9
WHITE BLOOD CELLS	133	7	5.3	1	0.8	125	94.0	131	3	2.3	1	0.8	127	96.9	138	3	2.2	1	0.7	134	97.1

*Other=unaltered or changed within the normal range

総括報告書（5.3.5.1-7）Table 62

表 2.7.4.7-付録-62　血液生化学検査の変化量（232 試験）（1/2）

TVP-1012/232 Placebo-Controlled Phase			1 mg			2 mg			PLACEBO		
			N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*
	Parameter (unit)										
Renal Function	CREATININE (MG/DL)	Baseline	134	0.90	0.00	132	0.86	0.00	138	0.88	0.00
		week 14	118	0.87	-0.03	115	0.86	-0.00	120	0.88	-0.00
		Termination	132	0.88	-0.03	131	0.85	-0.02	137	0.87	-0.01
	UREA NITROGEN (mg/dL)	Baseline	134	16.43	0.00	132	15.84	0.00	138	15.82	0.00
		week 14	118	16.34	-0.28	115	15.84	-0.12	120	15.73	-0.12
		Termination	132	16.75	0.33	131	15.98	0.13	137	15.78	0.01
Liver Function	ALK' PHOSPHATASE (U/L)	Baseline	134	65.27	0.00	132	64.23	0.00	138	67.61	0.00
		week 14	118	65.50	-0.10	114	64.43	-0.07	119	66.72	-0.78
		Termination	130	66.62	1.32	131	65.07	0.75	137	66.74	-1.10
	BILIRUBIN (TOTAL) (mg/dL)	Baseline	134	0.62	0.00	132	0.57	0.00	138	0.66	0.00
		week 14	118	0.61	-0.01	115	0.56	-0.02	119	0.63	-0.02
		Termination	131	0.59	-0.03	131	0.55	-0.02	137	0.63	-0.03
	SGOT (AST) (U/L)	Baseline	134	22.76	0.00	132	20.53	0.00	138	21.44	0.00
		week 14	118	21.79	-1.37	115	21.01	0.40	119	21.91	0.51
		Termination	131	22.95	0.15	131	20.94	0.39	137	22.13	0.66
	SGPT (ALT) (U/L)	Baseline	134	21.72	0.00	132	21.39	0.00	138	22.60	0.00
		week 14	118	21.18	-1.00	115	19.97	-1.22	119	21.84	-0.88
		Termination	131	21.59	-0.21	131	20.37	-1.05	137	22.73	0.06
Electrolytes	CHLORIDE (MEQ/L)	Baseline	134	102.76	0.00	132	102.85	0.00	138	103.01	0.00
		week 14	118	102.22	-0.64	115	102.45	-0.31	120	102.49	-0.58
		Termination	132	102.47	-0.28	131	102.82	-0.01	137	103.10	0.08
	POTASSIUM (MEQ/L)	Baseline	134	4.21	0.00	132	4.24	0.00	138	4.19	0.00
		week 14	118	4.22	0.00	114	4.17	-0.06	119	4.21	0.03
		Termination	130	4.21	0.01	131	4.15	-0.08	136	4.21	0.01
	SODIUM (MEQ/L)	Baseline	134	140.24	0.00	132	140.58	0.00	138	140.41	0.00
		week 14	118	139.74	-0.53	115	139.50	-1.03	120	139.92	-0.58
		Termination	132	139.67	-0.51	131	139.86	-0.69	137	140.27	-0.12

*BL=Baseline

総括報告書（5.3.5.1-7）Table 57

表 2.7.4.7-付録-62　血液生化学検査の変化量（232 試験）（2/2）

TVP-1012/232 Placebo-Controlled Phase			1 mg			2 mg			PLACEBO		
			N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*	N	Mean	Mean Change From BL*
Other	ALBUMIN (G/DL)	Baseline	134	4.11	0.00	132	4.15	0.00	138	4.12	0.00
		week 14	118	4.06	-0.04	115	4.06	-0.10	119	4.09	-0.03
		Termination	131	4.10	-0.01	131	4.07	-0.08	137	4.09	-0.03
	CALCIUM (MG/DL)	Baseline	134	9.29	0.00	132	9.31	0.00	138	9.29	0.00
		week 14	118	9.23	-0.05	115	9.24	-0.06	120	9.29	-0.01
		Termination	132	9.27	-0.01	131	9.22	-0.10	137	9.26	-0.03
	CHOLESTEROL (mg/dL)	Baseline	134	196.23	0.00	132	208.62	0.00	138	200.79	0.00
		week 14	118	194.00	-2.19	115	196.09	-10.50	120	200.03	-1.28
		Termination	132	193.81	-1.98	131	197.80	-10.47	137	200.09	-0.58
	GGT (U/L)	Baseline	134	26.51	0.00	132	23.74	0.00	138	25.07	0.00
		week 14	118	25.37	-2.28	115	23.67	0.62	120	26.32	0.61
		Termination	132	26.89	0.30	131	23.21	-0.47	137	26.39	1.23
	GLUCOSE (MG/DL)	Baseline	134	104.74	0.00	132	99.31	0.00	138	103.85	0.00
		week 14	118	101.70	-2.66	115	99.85	1.15	119	100.59	-3.76
		Termination	131	103.92	-0.77	131	100.11	0.77	136	99.62	-4.47
	LDH (U/L)	Baseline	134	157.46	0.00	132	157.31	0.00	138	153.09	0.00
		week 14	118	152.14	-4.64	114	156.46	-0.71	119	152.34	-0.16
		Termination	130	153.69	-3.41	131	158.05	0.85	136	153.51	0.35
	PHOSPHORUS (MG/DL)	Baseline	134	3.33	0.00	132	3.31	0.00	138	3.35	0.00
		week 14	118	3.37	0.02	114	3.31	0.02	119	3.31	-0.04
		Termination	130	3.38	0.06	131	3.32	0.00	136	3.30	-0.04
	PROTEIN (TOTAL) (G/DL)	Baseline	134	7.09	0.00	132	7.09	0.00	138	7.02	0.00
		week 14	118	7.05	-0.05	115	6.97	-0.12	120	6.96	-0.06
		Termination	132	7.07	-0.03	131	6.97	-0.11	137	7.01	-0.01

*BL=Baseline

総括報告書（5.3.5.1-7）Table 57

表 2.7.4.7-付録-63　血液生化学検査の正異判定のクロス表（232 試験）

TVP-1012/232 Placebo-Controlled Phase		A Shift Analysis from Baseline to Last Observed Value																				
		1 mg							2 mg							PLACEBO						
		All	Change From High/ Normal to Low		Change From Low/ Normal to High		Other*		All	Change From High/ Normal to Low		Change From Low/ Normal to High		Other*		All	Change From High/ Normal to Low		Change From Low / Normal to High		Other*	
			N	%	N	%	N	%		N	%	N	%	N	%		N	%	N	%	N	%
Renal Function	CREATININE	133	.	.	6	4.5	127	95.5	131	.	.	1	0.8	130	99.2	138	.	.	3	2.2	135	97.8
	UREA NITROGEN	133	.	.	6	4.5	127	95.5	131	.	.	5	3.8	126	96.2	138	.	.	.	.	138	100.0
Liver Function	ALK' PHOSPHATASE	133	1	0.8	2	1.5	130	97.7	131	.	.	.	.	131	100.0	138	2	1.4	1	0.7	135	97.8
	BILIRUBIN (TOTAL)	133	.	.	1	0.8	132	99.2	131	.	.	2	1.5	129	98.5	138	.	.	4	2.9	134	97.1
	SGOT (AST)	133	1	0.8	4	3.0	128	96.2	131	.	.	.	.	131	100.0	138	1	0.7	5	3.6	132	95.7
	SGPT (ALT)	133	.	.	5	3.8	128	96.2	131	.	.	2	1.5	129	98.5	138	.	.	3	2.2	135	97.8
Electrolytes	CHLORIDE	133	1	0.8	.	.	132	99.2	131	.	.	.	.	131	100.0	138	.	.	.	.	138	100.0
	POTASSIUM	133	1	0.8	1	0.8	131	98.5	131	.	.	.	.	131	100.0	137	.	.	.	.	137	100.0
	SODIUM	133	3	2.3	1	0.8	129	97.0	131	2	1.5	1	0.8	128	97.7	138	1	0.7	4	2.9	133	96.4
Other	ALBUMIN	133	2	1.5	.	.	131	98.5	131	1	0.8	.	.	130	99.2	138	.	.	.	.	138	100.0
	CALCIUM	133	1	0.8	1	0.8	131	98.5	131	.	.	.	.	131	100.0	138	1	0.7	.	.	137	99.3
	CHOLESTEROL	133	13	9.8	3	2.3	117	88.0	131	12	9.2	.	.	119	90.8	138	13	9.4	1	0.7	124	89.9
	GGT	133	.	.	2	1.5	131	98.5	131	.	.	4	3.1	127	96.9	138	1	0.7	5	3.6	132	95.7
	GLUCOSE	133	1	0.8	15	11.3	117	88.0	131	7	5.3	14	10.7	110	84.0	137	4	2.9	7	5.1	126	92.0
	LDH	133	.	.	.	.	133	100.0	131	.	.	1	0.8	130	99.2	137	.	.	1	0.7	136	99.3
	PHOSPHORUS	133	1	0.8	.	.	132	99.2	131	1	0.8	.	.	130	99.2	137	1	0.7	.	.	136	99.3
	PROTEIN (TOTAL)	133	.	.	1	0.8	132	99.2	131	2	1.5	.	.	129	98.5	138	.	.	.	.	138	100.0

*Other=unaltered or changed within the normal range

総括報告書（5.3.5.1-7）Table 58

表 2.7.4.7-付録-64　尿検査の正異判定のクロス表（232 試験）

TVP-1012/232 Placebo-Controlled Phase	1 mg							2 mg							PLACEBO						
	All	Change From Abnormal to Normal		Change From Normal to Abnormal		No Change		All	Change From Abnormal to Normal		Change From Normal to Abnormal		No Change		All	Change From Abnormal to Normal		Change From Normal to Abnormal		No Change	
		N	%	N	%	N	%		N	%	N	%	N	%		N	%	N	%	N	%
Parameter																					
URINE CASTS	131	.	.	.	.	131	100.0	129	.	.	.	.	129	100.0	138	.	.	.	.	138	100.0
URINE GLUCOSE	131	.	.	.	.	131	100.0	129	.	.	3	2.3	126	97.7	138	.	.	.	.	138	100.0
URINE KETONES	131	1	0.8	.	.	130	99.2	129	1	0.8	.	.	128	99.2	138	1	0.7	.	.	137	99.3
URINE OCCULT BLOOD	131	2	1.5	8	6.1	121	92.4	129	5	3.9	4	3.1	120	93.0	138	5	3.6	10	7.2	123	89.1
URINE pH	131	.	.	.	.	131	100.0	129	.	.	.	.	129	100.0	138	.	.	.	.	138	100.0
URINE PROTEIN	131	2	1.5	1	0.8	128	97.7	129	1	0.8	3	2.3	125	96.9	138	2	1.4	1	0.7	135	97.8
URINE RBC	131	3	2.3	2	1.5	126	96.2	129	4	3.1	3	2.3	122	94.6	138	7	5.1	5	3.6	126	91.3
URINE WBC	131	1	0.8	5	3.8	125	95.4	129	1	0.8	2	1.6	126	97.7	138	2	1.4	6	4.3	130	94.2

総括報告書（5.3.5.1-7）Table 65

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（1/30）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	424.7		423.7		420.6	
SD	40.55		42.03		45.99	
Minimum	333		334		200	
Q1	403.0		394.0		391.0	
Median	424.0		421.0		419.0	
Q3	449.0		449.0		454.0	
Maximum	533		533		524	
Week 3						
N	141	141	133	133	127	127
Mean	425.2	0.5	423.7	0.0	421.2	-1.4
SD	40.63	15.14	41.87	14.80	43.41	14.85
Minimum	327	-32	335	-52	323	-41
Q1	397.0	-10.0	393.0	-8.0	390.0	-12.0
Median	424.0	0.0	420.0	1.0	418.0	-1.0
Q3	455.0	10.0	447.0	7.0	452.0	7.0
Maximum	523	53	530	36	521	44

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（2/30）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	423.9	-0.4	424.8	0.1	425.3	1.3
SD	41.26	18.15	44.18	16.41	42.61	15.84
Minimum	318	-48	340	-38	312	-31
Q1	398.0	-13.0	390.0	-10.0	396.0	-10.0
Median	422.0	-1.0	426.0	0.0	422.5	1.0
Q3	450.0	13.0	447.0	11.0	456.0	12.0
Maximum	523	45	537	56	535	43
Week 14						
N	129	129	121	121	112	112
Mean	424.3	-0.2	425.5	-0.8	425.6	-0.6
SD	39.68	18.71	42.70	18.15	43.76	14.76
Minimum	329	-60	329	-45	327	-61
Q1	401.0	-12.0	397.0	-13.0	391.5	-10.0
Median	424.0	2.0	425.0	-1.0	423.0	1.0
Q3	451.0	12.0	454.0	10.0	458.5	9.5
Maximum	520	62	538	41	535	30

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（3/30）

Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	424.6	-1.6	423.1	-3.5	422.9	-2.8
SD	39.90	20.39	45.91	20.94	45.72	17.92
Minimum	330	-69	290	-93	323	-45
Q1	398.0	-14.0	396.0	-16.0	387.5	-16.0
Median	425.0	-4.0	420.5	-6.0	424.0	-1.0
Q3	447.0	11.0	451.0	10.0	457.0	8.0
Maximum	529	52	535	70	539	40
Week 26						
N	120	120	107	107	105	105
Mean	423.5	-4.2	421.3	-5.3	425.9	-0.8
SD	37.05	21.78	44.76	20.58	45.18	18.90
Minimum	323	-103	278	-80	323	-43
Q1	400.0	-16.0	390.0	-20.0	395.0	-13.0
Median	421.5	-3.0	422.0	-3.0	421.0	-2.0
Q3	449.0	10.5	453.0	7.0	461.0	11.0
Maximum	507	49	516	38	537	57

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（4/30）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	13.10		13.12		12.93	
SD	1.304		1.331		1.433	
Minimum	10.0		9.4		5.3	
Q1	12.30		12.30		12.10	
Median	13.20		13.00		12.90	
Q3	14.00		14.00		13.80	
Maximum	16.8		16.2		15.9	
Week 3						
N	141	141	133	133	127	127
Mean	13.09	-0.01	13.11	-0.01	12.95	-0.05
SD	1.270	0.446	1.340	0.429	1.303	0.438
Minimum	9.9	-1.1	9.3	-1.2	9.2	-1.2
Q1	12.30	-0.30	12.30	-0.30	12.10	-0.40
Median	13.10	0.00	13.10	0.00	12.90	0.00
Q3	14.10	0.20	13.90	0.20	13.70	0.20
Maximum	16.5	1.2	15.9	1.1	15.7	1.2

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（5/30）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	13.04	-0.05	13.08	-0.05	13.05	-0.02
SD	1.330	0.494	1.426	0.517	1.245	0.493
Minimum	10.0	-1.4	8.9	-1.5	9.5	-1.2
Q1	12.10	-0.40	12.20	-0.40	12.20	-0.40
Median	13.10	-0.10	12.90	0.00	12.90	0.00
Q3	13.90	0.30	14.00	0.30	13.90	0.30
Maximum	16.6	1.0	16.3	1.5	16.0	1.1
Week 14						
N	129	129	121	121	112	112
Mean	13.01	-0.09	13.02	-0.14	12.96	-0.14
SD	1.303	0.583	1.397	0.545	1.300	0.436
Minimum	9.9	-1.9	9.5	-1.3	9.7	-1.5
Q1	12.20	-0.40	12.10	-0.40	12.10	-0.40
Median	13.10	-0.10	13.00	-0.10	12.80	-0.10
Q3	13.90	0.30	13.90	0.20	13.75	0.10
Maximum	16.2	1.9	16.2	1.3	15.9	1.0

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（6/30）

Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	12.95	-0.20	12.86	-0.29	12.83	-0.27
SD	1.307	0.635	1.507	0.668	1.301	0.535
Minimum	9.6	-2.0	8.1	-3.1	9.8	-1.7
Q1	12.30	-0.60	11.80	-0.60	11.90	-0.60
Median	13.00	-0.30	12.90	-0.30	12.85	-0.30
Q3	13.90	0.30	13.90	0.10	13.75	0.10
Maximum	16.3	1.4	16.1	2.0	15.9	1.2
Week 26						
N	120	120	107	107	105	105
Mean	12.95	-0.24	12.79	-0.33	12.93	-0.18
SD	1.237	0.700	1.486	0.677	1.303	0.568
Minimum	9.8	-3.4	6.5	-2.9	10.1	-1.6
Q1	12.20	-0.70	11.80	-0.70	12.10	-0.50
Median	13.00	-0.20	12.90	-0.30	12.80	-0.20
Q3	13.70	0.20	13.90	0.10	13.90	0.20
Maximum	15.6	1.5	16.0	1.0	15.9	1.5

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（7/30）

Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	39.65		39.70		39.18	
SD	3.770		4.046		4.270	
Minimum	30.5		29.1		17.2	
Q1	37.50		37.00		37.10	
Median	39.70		39.70		39.00	
Q3	42.40		42.20		41.90	
Maximum	50.8		49.5		47.4	
Week 3						
N	141	141	133	133	127	127
Mean	39.47	-0.18	39.59	-0.11	39.14	-0.23
SD	3.688	1.425	3.960	1.466	3.926	1.364
Minimum	29.4	-4.5	28.5	-4.0	27.5	-3.8
Q1	36.90	-1.10	37.20	-1.00	36.70	-1.00
Median	39.30	-0.30	39.60	-0.10	38.90	-0.40
Q3	42.40	0.70	42.00	0.70	41.60	0.50
Maximum	48.9	3.9	48.2	3.4	47.0	4.3

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（8/30）

Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	39.27	-0.36	39.53	-0.20	39.37	-0.19
SD	3.910	1.693	4.228	1.630	3.749	1.485
Minimum	29.9	-4.5	28.2	-3.9	28.3	-3.6
Q1	36.40	-1.60	36.50	-1.30	36.90	-1.10
Median	39.30	-0.30	39.00	-0.20	39.10	-0.20
Q3	41.80	0.90	42.50	1.00	42.20	0.80
Maximum	49.6	3.2	50.6	4.0	48.1	3.4
Week 14						
N	129	129	121	121	112	112
Mean	39.14	-0.51	39.36	-0.48	39.11	-0.59
SD	3.762	1.901	4.180	1.808	3.918	1.533
Minimum	29.5	-4.9	29.9	-4.5	29.8	-5.2
Q1	36.60	-1.80	36.40	-1.50	36.55	-1.60
Median	39.40	-0.70	39.20	-0.40	38.80	-0.55
Q3	41.50	0.60	42.00	0.80	41.90	0.40
Maximum	48.4	6.3	49.6	4.7	47.3	2.9

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（9/30）

Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	39.02	-0.78	38.93	-0.90	38.72	-0.95
SD	3.822	2.036	4.439	2.198	3.973	1.748
Minimum	29.1	-6.0	25.7	-8.9	30.3	-5.8
Q1	36.40	-2.30	35.90	-2.20	36.20	-2.20
Median	39.30	-0.90	39.00	-1.10	38.50	-0.90
Q3	41.70	0.50	42.20	0.40	41.95	0.20
Maximum	48.5	4.2	49.8	7.1	48.8	3.9
Week 26						
N	120	120	107	107	105	105
Mean	38.87	-1.05	38.52	-1.23	38.88	-0.86
SD	3.580	2.161	4.344	2.173	3.922	1.954
Minimum	29.1	-8.8	21.1	-8.0	30.6	-5.3
Q1	36.75	-2.30	35.90	-2.60	36.20	-2.10
Median	39.00	-1.25	38.70	-1.20	38.60	-1.10
Q3	41.25	0.40	41.60	0.30	42.30	0.60
Maximum	46.8	4.8	47.9	3.1	48.1	3.4

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（10/30）

Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	5405.0		5512.0		5649.6	
SD	1455.65		1727.59		1540.20	
Minimum	2200		2300		2400	
Q1	4400.0		4300.0		4800.0	
Median	5100.0		5200.0		5500.0	
Q3	6200.0		6400.0		6300.0	
Maximum	9600		12000		10500	
Week 3						
N	141	141	133	133	127	127
Mean	5431.9	27.0	5531.6	19.5	5569.3	-82.7
SD	1523.97	999.56	1619.73	1133.88	1494.41	1254.71
Minimum	2200	-4000	2300	-5400	2700	-3700
Q1	4300.0	-500.0	4400.0	-600.0	4700.0	-600.0
Median	5300.0	100.0	5300.0	100.0	5400.0	-100.0
Q3	6300.0	500.0	6600.0	600.0	6500.0	400.0
Maximum	10600	3100	10100	3500	11600	5500

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（11/30）

Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	5456.1	47.5	5595.3	79.5	5752.5	15.6
SD	1529.81	995.59	1580.88	1276.36	1497.01	1377.69
Minimum	2500	-2800	2200	-5000	2600	-3800
Q1	4300.0	-600.0	4500.0	-500.0	4800.0	-700.0
Median	5300.0	0.0	5500.0	100.0	5500.0	-100.0
Q3	6300.0	600.0	6500.0	900.0	6600.0	700.0
Maximum	10200	2800	11300	5600	11900	7100
Week 14						
N	129	129	121	121	112	112
Mean	5496.1	110.9	5561.2	31.4	5605.4	-162.5
SD	1577.55	1073.93	1535.76	1206.51	1440.65	1088.53
Minimum	3000	-3900	2600	-4900	2200	-3700
Q1	4300.0	-600.0	4500.0	-500.0	4500.0	-650.0
Median	5400.0	200.0	5300.0	100.0	5300.0	-250.0
Q3	6300.0	700.0	6600.0	600.0	6650.0	400.0
Maximum	11800	5000	11600	3300	10200	2600

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（12/30）

Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	5535.8	185.4	5668.2	106.4	5569.4	-189.8
SD	1535.49	1229.33	1765.73	1373.56	1398.69	1238.10
Minimum	2600	-3500	2200	-5400	2700	-3700
Q1	4300.0	-500.0	4500.0	-700.0	4600.0	-900.0
Median	5200.0	0.0	5350.0	50.0	5450.0	-100.0
Q3	6600.0	900.0	6600.0	800.0	6450.0	700.0
Maximum	10000	4600	11900	5300	10400	2700
Week 26						
N	120	120	107	107	105	105
Mean	5579.2	218.3	5535.5	23.4	5750.5	-33.3
SD	1718.95	1324.49	1678.74	1289.04	1582.18	1177.81
Minimum	2500	-4000	2300	-5800	2300	-3900
Q1	4350.0	-500.0	4400.0	-600.0	4600.0	-600.0
Median	5300.0	100.0	5500.0	0.0	5400.0	-100.0
Q3	6350.0	950.0	6300.0	700.0	6800.0	700.0
Maximum	12800	6400	13800	3500	10900	3700

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（13/30）

Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	63.39		64.10		64.07	
SD	8.440		7.889		9.063	
Minimum	42.5		35.7		33.6	
Q1	57.50		59.30		59.50	
Median	64.10		64.40		64.20	
Q3	69.00		68.70		70.80	
Maximum	81.5		81.5		85.5	
Week 3						
N	141	141	133	133	126	126
Mean	63.27	-0.12	63.92	-0.18	63.39	-0.68
SD	8.258	6.753	8.394	6.859	9.140	6.791
Minimum	36.5	-31.9	45.5	-15.4	43.8	-14.9
Q1	58.00	-4.10	58.50	-3.50	56.60	-5.50
Median	63.90	-0.30	63.30	-0.80	63.80	-1.25
Q3	68.10	3.80	70.00	3.10	69.70	3.70
Maximum	82.8	18.8	87.7	38.6	87.6	19.9

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（14/30）

Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	63.64	0.32	64.44	0.37	64.07	-0.03
SD	8.094	6.009	9.263	7.720	9.326	7.369
Minimum	38.9	-19.5	35.7	-17.8	41.0	-17.0
Q1	57.80	-3.60	58.20	-3.40	57.90	-4.00
Median	64.50	0.60	65.10	0.00	64.40	-1.35
Q3	68.80	3.90	70.50	4.80	70.10	4.10
Maximum	84.0	17.4	83.5	46.4	86.7	21.9
Week 14						
N	129	129	121	121	111	111
Mean	63.63	0.71	64.30	0.35	63.45	-0.77
SD	8.166	7.050	8.156	7.224	8.354	7.118
Minimum	33.4	-13.6	43.6	-13.6	42.1	-16.5
Q1	58.20	-4.10	58.50	-4.40	57.40	-5.10
Median	63.30	0.90	64.70	0.50	62.80	-0.50
Q3	68.80	4.70	69.80	4.50	70.40	3.30
Maximum	82.5	20.8	84.5	33.2	85.5	23.2

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（15/30）

Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	122	122	110	110	107	107
Mean	64.30	1.55	64.08	-0.21	63.24	-1.03
SD	8.725	8.499	8.160	7.867	8.859	7.720
Minimum	46.1	-18.7	45.9	-26.8	36.9	-21.0
Q1	58.00	-3.30	58.20	-5.00	57.00	-6.40
Median	63.95	0.55	62.90	-1.30	62.00	-1.20
Q3	70.60	5.20	70.50	4.60	70.00	4.50
Maximum	89.2	32.8	87.0	32.0	86.5	16.8
Week 26						
N	120	120	107	107	104	104
Mean	63.89	1.19	63.60	-0.60	64.05	-0.36
SD	8.994	8.202	8.378	7.020	8.544	7.761
Minimum	32.0	-28.1	39.3	-23.4	43.4	-22.1
Q1	58.05	-3.60	58.70	-3.70	57.60	-5.30
Median	64.95	1.10	64.00	-1.00	64.00	-1.45
Q3	70.20	5.85	69.30	4.00	68.65	4.00
Maximum	88.5	30.0	82.5	18.3	86.0	29.9

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（16/30）

Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	2.29		1.98		2.14	
SD	2.257		1.607		1.727	
Minimum	0.0		0.0		0.0	
Q1	0.80		1.00		0.90	
Median	1.80		1.60		1.90	
Q3	3.00		2.60		3.00	
Maximum	17.0		8.6		9.5	
Week 3						
N	141	141	133	133	126	126
Mean	2.24	-0.05	2.06	0.09	2.23	0.08
SD	1.807	1.454	1.736	1.246	1.870	1.220
Minimum	0.0	-10.9	0.0	-7.0	0.0	-3.5
Q1	1.00	-0.70	1.00	-0.50	0.90	-0.50
Median	1.70	0.00	1.60	0.00	1.55	0.10
Q3	2.90	0.60	2.70	0.50	3.00	0.60
Maximum	7.5	4.3	9.7	4.3	8.3	4.0

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（17/30）

Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	2.23	-0.07	2.17	0.15	2.18	0.06
SD	2.001	1.272	2.116	1.737	1.759	1.174
Minimum	0.0	-6.5	0.0	-6.6	0.0	-4.5
Q1	0.80	-0.50	0.90	-0.70	1.00	-0.50
Median	1.60	0.00	1.60	0.00	1.70	0.00
Q3	2.90	0.70	3.00	0.80	3.00	0.60
Maximum	10.5	3.7	14.2	8.0	10.0	5.2
Week 14						
N	129	129	121	121	111	111
Mean	2.37	0.03	1.95	-0.11	2.30	0.13
SD	2.567	2.221	1.452	1.315	1.965	1.789
Minimum	0.0	-10.2	0.0	-6.6	0.0	-4.2
Q1	0.90	-0.70	1.00	-0.70	1.00	-0.80
Median	1.60	-0.10	1.50	0.00	1.60	0.10
Q3	2.80	0.50	2.70	0.50	3.00	0.90
Maximum	19.1	16.8	7.9	3.5	10.7	9.7

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（18/30）

Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Week 20						
N	122	122	110	110	107	107
Mean	2.10	-0.24	2.19	0.10	2.41	0.24
SD	1.910	1.785	2.623	2.322	2.181	1.883
Minimum	0.0	-11.5	0.0	-7.0	0.0	-6.5
Q1	0.90	-0.70	0.90	-0.60	1.00	-0.50
Median	1.50	0.00	1.65	0.00	1.80	0.10
Q3	2.80	0.50	2.70	0.40	3.10	0.70
Maximum	9.0	6.1	23.0	19.1	13.1	8.3
Week 26						
N	120	120	107	107	104	104
Mean	2.29	-0.09	2.11	0.00	2.42	0.23
SD	2.181	1.706	1.841	1.499	1.783	1.610
Minimum	0.0	-8.5	0.0	-6.0	0.4	-6.5
Q1	1.00	-0.80	1.00	-0.60	1.10	-0.60
Median	1.60	0.00	1.80	-0.10	2.00	0.25
Q3	2.90	0.55	2.70	0.60	3.05	1.05
Maximum	11.1	6.7	12.1	6.0	9.0	4.8

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（19/30）

Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	6.15		5.88		5.91	
SD	1.741		1.850		1.724	
Minimum	2.0		1.8		1.8	
Q1	4.90		4.50		4.80	
Median	6.00		6.00		5.90	
Q3	7.30		7.10		7.00	
Maximum	11.0		11.7		10.4	
Week 3						
N	141	141	133	133	126	126
Mean	5.95	-0.20	5.93	0.05	5.97	0.05
SD	1.751	1.434	1.674	1.754	1.848	1.543
Minimum	2.6	-4.0	1.2	-6.3	1.5	-4.1
Q1	4.70	-1.00	4.90	-1.00	4.70	-0.90
Median	5.80	-0.10	5.90	0.00	5.80	0.10
Q3	7.10	0.70	7.20	1.00	7.10	1.00
Maximum	10.8	3.1	9.4	5.0	12.2	4.2

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（20/30）

Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	6.00	-0.16	5.85	-0.05	6.04	0.20
SD	1.979	1.843	1.688	1.885	1.741	1.541
Minimum	1.5	-3.9	1.5	-8.4	1.6	-4.8
Q1	4.70	-1.30	4.70	-1.10	5.00	-0.70
Median	5.80	-0.40	5.80	0.10	5.95	0.20
Q3	7.20	0.90	7.00	0.90	7.30	1.10
Maximum	12.9	7.6	9.6	5.0	9.8	4.5
Week 14						
N	129	129	121	121	111	111
Mean	6.07	-0.13	5.80	-0.07	6.02	0.17
SD	1.724	1.530	1.659	1.684	1.654	1.526
Minimum	2.0	-4.8	1.6	-6.5	2.0	-4.0
Q1	5.00	-1.00	5.00	-1.10	5.00	-0.90
Median	6.10	0.10	5.90	0.10	5.80	0.20
Q3	7.30	1.00	6.70	1.00	7.20	1.20
Maximum	11.4	4.0	10.4	3.7	10.5	4.2

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（21/30）

Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	122	122	110	110	107	107
Mean	5.92	-0.29	5.90	0.13	6.14	0.30
SD	1.910	1.879	1.819	1.737	1.725	1.649
Minimum	1.7	-5.8	2.0	-4.0	3.0	-3.5
Q1	4.60	-1.30	4.70	-0.90	5.00	-0.90
Median	5.80	-0.25	5.80	0.25	6.00	0.10
Q3	7.10	1.00	7.10	1.10	7.00	1.50
Maximum	11.6	3.9	10.5	5.5	11.7	4.0
Week 26						
N	120	120	107	107	104	104
Mean	5.82	-0.41	5.89	0.15	6.03	0.21
SD	1.624	1.621	1.632	1.637	1.509	1.568
Minimum	1.9	-5.9	2.6	-4.4	2.0	-4.6
Q1	4.60	-1.40	4.60	-0.70	5.00	-0.70
Median	5.75	-0.35	5.90	0.20	6.00	0.35
Q3	7.00	0.60	7.00	1.00	7.00	1.30
Maximum	9.9	3.8	10.5	4.0	9.6	3.5

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（22/30）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	27.79		27.64		27.51	
SD	7.267		6.867		8.145	
Minimum	13.5		11.5		9.5	
Q1	23.00		22.60		21.90	
Median	26.90		27.00		27.00	
Q3	32.20		32.80		31.80	
Maximum	51.2		48.9		49.7	
Week 3						
N	141	141	133	133	126	126
Mean	28.14	0.35	27.66	0.03	28.03	0.55
SD	7.507	5.681	7.534	5.880	8.203	5.769
Minimum	11.4	-16.6	10.2	-30.8	7.2	-17.6
Q1	22.50	-2.70	22.70	-3.00	23.00	-2.50
Median	27.10	0.50	28.00	0.20	27.30	0.75
Q3	32.80	3.70	32.90	2.90	33.90	3.80
Maximum	53.5	28.6	46.0	16.5	49.4	14.6

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（23/30）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	27.69	-0.13	27.14	-0.46	27.32	-0.23
SD	7.094	5.138	7.881	6.402	8.526	6.621
Minimum	12.8	-15.0	10.0	-36.0	9.1	-17.1
Q1	22.90	-3.30	22.00	-3.90	21.30	-3.40
Median	27.30	0.00	26.50	-0.60	26.55	0.40
Q3	31.80	3.00	33.10	3.00	32.70	3.50
Maximum	51.5	20.1	54.0	16.9	52.1	16.0
Week 14						
N	129	129	121	121	111	111
Mean	27.52	-0.64	27.50	-0.24	27.86	0.49
SD	6.602	5.847	7.369	6.101	7.727	5.983
Minimum	13.0	-16.5	9.0	-24.5	10.0	-16.8
Q1	24.00	-4.40	22.30	-3.40	22.00	-3.50
Median	27.00	-0.20	26.80	0.20	27.60	0.40
Q3	32.30	3.30	32.40	3.30	33.90	4.40
Maximum	42.3	11.9	46.4	15.0	44.9	12.3

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（24/30）

Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	122	122	110	110	107	107
Mean	27.30	-1.00	27.39	-0.07	27.88	0.54
SD	7.616	6.928	6.910	6.872	7.908	6.337
Minimum	8.0	-25.3	10.5	-26.8	10.5	-15.2
Q1	23.20	-4.00	21.70	-4.40	22.40	-4.20
Median	27.70	-0.60	27.95	0.30	27.90	0.70
Q3	31.50	2.60	32.70	4.00	33.60	5.00
Maximum	45.1	17.0	44.3	23.3	50.8	17.4
Week 26						
N	120	120	107	107	104	104
Mean	27.63	-0.67	27.98	0.40	27.09	-0.11
SD	7.892	6.736	7.259	5.778	7.716	6.823
Minimum	8.0	-21.2	13.0	-16.8	9.5	-28.3
Q1	22.25	-4.45	23.10	-2.80	22.00	-4.10
Median	27.40	-0.50	27.60	0.10	26.40	0.50
Q3	33.40	3.55	32.00	3.20	31.80	4.75
Maximum	54.0	22.6	51.6	20.2	48.3	17.7

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（25/30）

Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	0.38		0.40		0.38	
SD	0.337		0.373		0.276	
Minimum	0.0		0.0		0.0	
Q1	0.20		0.20		0.20	
Median	0.40		0.30		0.30	
Q3	0.50		0.60		0.50	
Maximum	2.4		2.4		1.3	
Week 3						
N	141	141	133	133	126	126
Mean	0.40	0.02	0.42	0.02	0.37	0.00
SD	0.321	0.440	0.317	0.459	0.282	0.367
Minimum	0.0	-2.4	0.0	-1.9	0.0	-1.1
Q1	0.20	-0.20	0.20	-0.20	0.20	-0.20
Median	0.40	0.00	0.40	0.00	0.35	0.00
Q3	0.50	0.20	0.60	0.30	0.50	0.20
Maximum	2.3	2.0	1.4	1.0	2.0	1.5

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（26/30）

Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	0.43	0.05	0.40	0.00	0.39	0.00
SD	0.317	0.482	0.342	0.484	0.285	0.384
Minimum	0.0	-2.1	0.0	-2.1	0.0	-1.1
Q1	0.20	-0.20	0.10	-0.30	0.20	-0.20
Median	0.40	0.00	0.40	0.00	0.30	0.00
Q3	0.50	0.30	0.60	0.30	0.50	0.20
Maximum	1.9	1.4	1.8	1.5	1.1	1.0
Week 14						
N	129	129	121	121	111	111
Mean	0.41	0.02	0.46	0.07	0.36	-0.02
SD	0.281	0.402	0.366	0.498	0.305	0.413
Minimum	0.0	-1.7	0.0	-2.0	0.0	-1.3
Q1	0.20	-0.20	0.20	-0.20	0.20	-0.20
Median	0.40	0.00	0.40	0.10	0.30	0.00
Q3	0.50	0.20	0.60	0.30	0.50	0.20
Maximum	1.1	1.1	1.5	1.3	1.3	1.0

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（27/30）

Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	122	122	110	110	107	107
Mean	0.38	-0.02	0.43	0.05	0.33	-0.05
SD	0.351	0.413	0.329	0.507	0.292	0.411
Minimum	0.0	-1.6	0.0	-2.4	0.0	-1.1
Q1	0.20	-0.20	0.20	-0.20	0.10	-0.30
Median	0.30	0.00	0.40	0.00	0.30	0.00
Q3	0.50	0.20	0.60	0.30	0.50	0.20
Maximum	2.0	1.0	1.8	1.8	1.3	1.0
Week 26						
N	120	120	107	107	104	104
Mean	0.38	-0.03	0.42	0.04	0.42	0.03
SD	0.283	0.436	0.361	0.491	0.413	0.458
Minimum	0.0	-2.3	0.0	-2.1	0.0	-1.0
Q1	0.20	-0.20	0.10	-0.20	0.20	-0.20
Median	0.40	0.00	0.40	0.00	0.30	0.00
Q3	0.50	0.20	0.60	0.30	0.50	0.20
Maximum	1.7	1.2	2.0	1.6	2.4	2.0

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（28/30）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	137		131		127	
Mean	21.42		21.62		22.73	
SD	5.279		4.595		5.873	
Minimum	11.0		12.0		12.6	
Q1	17.90		18.60		18.80	
Median	21.20		21.20		21.80	
Q3	24.00		24.10		26.80	
Maximum	44.5		41.1		48.3	
Week 3						
N	139	136	130	129	127	125
Mean	21.73	0.31	21.49	-0.15	22.32	-0.24
SD	5.188	2.212	4.232	2.138	5.078	2.346
Minimum	10.9	-13.4	11.5	-7.5	12.6	-9.7
Q1	17.90	-0.90	18.10	-1.70	18.20	-1.40
Median	21.40	0.40	21.05	-0.10	21.90	-0.20
Q3	25.10	1.45	23.90	1.40	25.60	0.90
Maximum	41.2	7.4	36.4	4.1	37.4	8.3

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（29/30）

Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	135	124	123	120	120
Mean	21.59	0.33	21.56	-0.08	22.76	0.10
SD	5.387	2.411	4.590	2.498	5.252	2.683
Minimum	12.0	-10.4	11.4	-7.4	11.3	-11.2
Q1	18.00	-0.90	17.95	-1.50	19.20	-1.30
Median	20.80	0.20	21.45	-0.30	22.90	-0.05
Q3	24.60	1.50	24.00	1.30	25.70	1.45
Maximum	42.0	10.3	39.2	13.8	40.0	12.3
Week 14						
N	129	125	118	118	109	109
Mean	22.01	0.74	21.67	0.00	23.16	0.23
SD	5.347	2.756	4.453	2.781	5.417	3.313
Minimum	12.8	-4.8	12.6	-6.6	12.8	-9.9
Q1	18.40	-0.90	18.30	-1.30	19.30	-1.20
Median	21.30	0.20	21.20	-0.20	22.30	0.00
Q3	24.60	2.00	24.00	1.50	27.20	1.60
Maximum	41.3	19.2	36.7	8.4	37.9	16.3

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-65　血液学的検査の評価時点別変化量（CCT-002 試験）（30/30）

Laboratory Test: Platelets (10^4/μL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	120	118	108	108	105	105
Mean	21.39	0.07	21.97	0.09	23.21	0.29
SD	5.178	2.234	4.891	3.243	5.506	2.898
Minimum	11.7	-7.4	11.2	-9.3	13.6	-12.5
Q1	18.20	-1.30	18.65	-1.95	19.00	-1.00
Median	21.05	-0.15	21.75	0.00	23.10	0.00
Q3	23.90	1.30	25.10	1.60	26.30	1.50
Maximum	45.8	11.3	36.9	14.2	43.4	10.1
Week 26						
N	118	116	105	105	102	102
Mean	21.43	0.23	21.59	-0.28	22.79	-0.12
SD	5.084	2.456	4.751	2.497	5.275	2.729
Minimum	13.0	-5.7	11.7	-8.3	11.0	-10.0
Q1	18.00	-1.40	18.50	-1.40	18.30	-1.50
Median	21.15	0.00	21.50	-0.30	23.10	0.00
Q3	23.90	1.60	24.00	1.20	26.50	1.60
Maximum	43.1	13.2	48.1	8.7	36.6	5.7

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（1/20）

RBC

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	33	2	-	35	28	7	-	35	26	5	-	31
Normal	4	102	-	106	9	89	-	98	3	90	1	94
High	-	-	-	-	-	-	-	-	-	1	1	2
Total	37	104	-	141	37	96	-	133	29	96	2	127
Week 6												
Low	34	6	-	40	28	8	-	36	23	7	-	30
Normal	3	96	-	99	7	84	-	91	3	87	1	91
High	-	-	-	-	-	-	-	-	-	-	1	1
Total	37	102	-	139	35	92	-	127	26	94	2	122
Week 14												
Low	28	7	-	35	27	6	-	33	19	6	-	25
Normal	6	88	-	94	5	83	-	88	3	81	2	86
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	34	95	-	129	32	89	-	121	22	88	2	112
Week 20												
Low	22	10	-	32	23	4	-	27	21	8	-	29
Normal	9	82	-	91	5	78	-	83	1	76	1	78
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	31	92	-	123	28	82	-	110	22	85	1	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（2/20）

RBC

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	22	8	-	30	21	7	-	28	18	9	-	27
Normal	7	83	-	90	6	73	-	79	2	73	1	76
High	-	-	-	-	-	-	-	-	-	2	-	2
Total	29	91	-	120	27	80	-	107	20	84	1	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（3/20）

Hemoglobin

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	27	5	-	32	23	7	-	30	27	6	-	33
Normal	5	104	-	109	1	102	-	103	3	91	-	94
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	32	109	-	141	24	109	-	133	30	97	-	127
Week 6												
Low	28	6	-	34	23	8	-	31	23	3	-	26
Normal	4	100	-	104	1	95	-	96	4	92	-	96
High	-	1	-	1	-	-	-	-	-	-	-	-
Total	32	107	-	139	24	103	-	127	27	95	-	122
Week 14												
Low	23	9	-	32	22	14	-	36	22	10	-	32
Normal	6	91	-	97	1	84	-	85	1	79	-	80
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	29	100	-	129	23	98	-	121	23	89	-	112
Week 20												
Low	20	11	-	31	21	16	-	37	22	14	-	36
Normal	6	86	-	92	2	71	-	73	1	71	-	72
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	26	97	-	123	23	87	-	110	23	85	-	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（4/20）

Hemoglobin

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	17	11	-	28	21	15	-	36	20	9	-	29
Normal	8	83	-	91	2	68	-	70	2	73	-	75
High	-	1	-	1	-	1	-	1	-	1	-	1
Total	25	95	-	120	23	84	-	107	22	83	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（5/20）

Hematocrit

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	21	6	-	27	23	5	-	28	27	2	-	29
Normal	4	109	-	113	3	102	-	105	3	95	-	98
High	-	1	-	1	-	-	-	-	-	-	-	-
Total	25	116	-	141	26	107	-	133	30	97	-	127
Week 6												
Low	20	10	-	30	21	7	-	28	20	5	-	25
Normal	5	101	-	106	3	96	-	99	7	89	-	96
High	-	3	-	3	-	-	-	-	-	1	-	1
Total	25	114	-	139	24	103	-	127	27	95	-	122
Week 14												
Low	16	15	-	31	21	8	-	29	20	8	-	28
Normal	6	91	-	97	2	90	-	92	3	81	-	84
High	-	1	-	1	-	-	-	-	-	-	-	-
Total	22	107	-	129	23	98	-	121	23	89	-	112
Week 20												
Low	16	12	-	28	20	11	-	31	21	14	-	35
Normal	4	91	-	95	2	77	-	79	2	71	-	73
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	20	103	-	123	22	88	-	110	23	85	-	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（6/20）

Hematocrit

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	15	11	-	26	19	16	-	35	20	9	-	29
Normal	4	90	-	94	3	69	-	72	2	73	-	75
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	19	101	-	120	22	85	-	107	22	83	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（7/20）

WBC

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	4	2	-	6	4	4	-	8	4	3	-	7
Normal	2	128	3	133	3	116	2	121	5	108	4	117
High	-	2	-	2	-	1	3	4	-	3	-	3
Total	6	132	3	141	7	121	5	133	9	114	4	127
Week 6												
Low	3	1	-	4	6	2	-	8	3	-	-	3
Normal	3	125	2	130	1	111	4	116	3	110	4	117
High	-	4	1	5	-	2	1	3	-	2	-	2
Total	6	130	3	139	7	115	5	127	6	112	4	122
Week 14												
Low	2	4	-	6	3	-	-	3	2	1	-	3
Normal	3	114	2	119	4	108	3	115	4	100	4	108
High	-	3	1	4	-	1	2	3	-	1	-	1
Total	5	121	3	129	7	109	5	121	6	102	4	112
Week 20												
Low	2	1	-	3	3	4	-	7	1	-	-	1
Normal	3	110	3	116	2	94	3	99	5	96	3	104
High	-	4	-	4	-	2	2	4	-	2	1	3
Total	5	115	3	123	5	100	5	110	6	98	4	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（8/20）

WBC

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	2	2	-	4	3	5	-	8	1	1	-	2
Normal	3	107	2	112	2	92	3	97	4	92	3	99
High	-	3	1	4	-	1	1	2	-	3	1	4
Total	5	112	3	120	5	98	4	107	5	96	4	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（9/20）

Neutrophils

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	2	-	2	-	-	-	-	-	-	-	-
Normal	-	123	7	130	1	120	3	124	1	105	5	111
High	-	5	4	9	-	3	6	9	-	8	7	15
Total	-	130	11	141	1	123	9	133	1	113	12	126
Week 6												
Low	-	1	-	1	-	1	-	1	-	-	-	-
Normal	-	123	6	129	-	109	4	113	-	100	6	106
High	-	4	5	9	1	8	4	13	-	10	6	16
Total	-	128	11	139	1	118	8	127	-	110	12	122
Week 14												
Low	-	1	-	1	-	-	-	-	-	-	-	-
Normal	-	111	6	117	1	106	4	111	-	91	8	99
High	-	7	4	11	-	6	4	10	-	8	4	12
Total	-	119	10	129	1	112	8	121	-	99	12	111
Week 20												
Low	-	-	-	-	-	-	-	-	-	1	-	1
Normal	-	104	7	111	-	96	5	101	-	91	6	97
High	-	9	2	11	-	8	1	9	-	3	6	9
Total	-	113	9	122	-	104	6	110	-	95	12	107

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（10/20）

Neutrophils

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	2	-	2	-	1	-	1	-	-	-	-
Normal	-	101	6	107	-	93	4	97	-	87	6	93
High	-	8	3	11	-	7	2	9	-	5	6	11
Total	-	111	9	120	-	101	6	107	-	92	12	104

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（11/20）

Eosinophils

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	138	3	141	-	131	-	131	-	124	1	125
High	-	-	-	-	-	1	1	2	-	1	-	1
Total	-	138	3	141	-	132	1	133	-	125	1	126
Week 6												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	134	2	136	-	124	-	124	-	119	1	120
High	-	2	1	3	-	2	1	3	-	2	-	2
Total	-	136	3	139	-	126	1	127	-	121	1	122
Week 14												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	123	2	125	-	120	1	121	-	107	1	108
High	-	3	1	4	-	-	-	-	-	3	-	3
Total	-	126	3	129	-	120	1	121	-	110	1	111
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	117	3	120	-	108	-	108	-	102	1	103
High	-	2	-	2	-	1	1	2	-	4	-	4
Total	-	119	3	122	-	109	1	110	-	106	1	107

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（12/20）

Eosinophils

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	113	2	115	-	106	-	106	-	101	1	102
High	-	4	1	5	-	-	1	1	-	2	-	2
Total	-	117	3	120	-	106	1	107	-	103	1	104

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（13/20）

Monocytes

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	-	-	-	-	1	-	1	-	1	-	1
Normal	-	138	2	140	1	128	3	132	1	122	1	124
High	-	-	1	1	-	-	-	-	-	1	-	1
Total	-	138	3	141	1	129	3	133	1	124	1	126
Week 6												
Low	-	1	-	1	-	1	-	1	-	1	-	1
Normal	-	131	2	133	1	122	3	126	1	119	1	121
High	-	4	1	5	-	-	-	-	-	-	-	-
Total	-	136	3	139	1	123	3	127	1	120	1	122
Week 14												
Low	-	-	-	-	-	1	-	1	-	-	-	-
Normal	-	126	1	127	1	115	3	119	1	107	1	109
High	-	-	2	2	-	1	-	1	-	2	-	2
Total	-	126	3	129	1	117	3	121	1	109	1	111
Week 20												
Low	-	1	-	1	-	-	-	-	-	-	-	-
Normal	-	118	1	119	1	105	2	108	1	102	1	104
High	-	-	2	2	-	2	-	2	-	3	-	3
Total	-	119	3	122	1	107	2	110	1	105	1	107

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（14/20）

Monocytes

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	1	-	1	-	-	-	-	-	-	-	-
Normal	-	116	3	119	1	103	2	106	1	102	1	104
High	-	-	-	-	-	1	-	1	-	-	-	-
Total	-	117	3	120	1	104	2	107	1	102	1	104

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（15/20）

Lymphocytes

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	6	4	-	10	5	8	-	13	8	7	-	15
Normal	7	121	-	128	1	119	-	120	6	104	-	110
High	-	2	1	3	-	-	-	-	-	-	1	1
Total	13	127	1	141	6	127	-	133	14	111	1	126
Week 6												
Low	7	2	-	9	3	11	-	14	6	8	-	14
Normal	6	122	1	129	2	110	-	112	8	99	-	107
High	-	1	-	1	-	1	-	1	-	-	1	1
Total	13	125	1	139	5	122	-	127	14	107	1	122
Week 14												
Low	4	7	-	11	3	5	-	8	6	7	-	13
Normal	5	112	1	118	2	111	-	113	8	89	1	98
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	9	119	1	129	5	116	-	121	14	96	1	111
Week 20												
Low	2	10	-	12	2	6	-	8	6	4	-	10
Normal	6	103	1	110	1	101	-	102	8	88	-	96
High	-	-	-	-	-	-	-	-	-	-	1	1
Total	8	113	1	122	3	107	-	110	14	92	1	107

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（16/20）

Lymphocytes

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	4	7	-	11	2	7	-	9	8	7	-	15
Normal	4	103	-	107	1	96	-	97	6	82	1	89
High	-	1	1	2	-	1	-	1	-	-	-	-
Total	8	111	1	120	3	104	-	107	14	89	1	104

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（17/20）

Basophils

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	139	1	140	-	132	1	133	-	126	-	126
High	-	1	-	1	-	-	-	-	-	-	-	-
Total	-	140	1	141	-	132	1	133	-	126	-	126
Week 6												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	138	1	139	-	126	1	127	-	122	-	122
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	138	1	139	-	126	1	127	-	122	-	122
Week 14												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	128	1	129	-	120	1	121	-	111	-	111
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	128	1	129	-	120	1	121	-	111	-	111
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	121	1	122	-	109	1	110	-	107	-	107
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	121	1	122	-	109	1	110	-	107	-	107

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（18/20）

Basophils

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	119	1	120	-	106	1	107	-	103	-	103
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	-	119	1	120	-	106	1	107	-	104	-	104

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（19/20）

Platelets

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	7	3	-	10	1	-	-	1	1	3	-	4
Normal	2	121	2	125	1	124	1	126	2	112	5	119
High	-	-	1	1	-	-	2	2	-	1	1	2
Total	9	124	3	136	2	124	3	129	3	116	6	125
Week 6												
Low	6	1	-	7	1	2	-	3	1	1	-	2
Normal	3	120	1	124	1	115	2	118	2	109	5	116
High	-	2	2	4	-	1	1	2	-	1	1	2
Total	9	123	3	135	2	118	3	123	3	111	6	120
Week 14												
Low	3	1	-	4	1	-	-	1	1	-	-	1
Normal	5	112	1	118	1	113	1	115	1	97	5	103
High	-	2	1	3	-	-	2	2	-	4	1	5
Total	8	115	2	125	2	113	3	118	2	101	6	109
Week 20												
Low	2	1	-	3	2	2	-	4	1	-	-	1
Normal	5	107	1	113	-	100	1	101	1	95	3	99
High	-	1	1	2	-	1	2	3	-	2	3	5
Total	7	109	2	118	2	103	3	108	2	97	6	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-66　血液学的検査の正異判定のクロス表（CCT-002 試験）（20/20）

Platelets

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	4	-	-	4	2	-	-	2	1	2	-	3
Normal	3	106	1	110	-	100	1	101	1	92	5	98
High	-	1	1	2	-	-	2	2	-	-	1	1
Total	7	107	2	116	2	100	3	105	2	94	6	102

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（1/57）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	23.2		24.2		22.2	
SD	5.51		6.82		5.05	
Minimum	14		15		10	
Q1	20.0		20.0		19.0	
Median	22.0		22.0		22.0	
Q3	26.0		27.0		25.0	
Maximum	53		57		49	
Week 3						
N	141	141	132	132	127	127
Mean	22.5	-0.7	25.0	0.8	23.8	1.7
SD	5.23	3.21	7.24	3.88	8.00	5.27
Minimum	14	-11	13	-7	11	-10
Q1	19.0	-2.0	20.0	-1.5	19.0	-1.0
Median	22.0	-1.0	23.0	1.0	22.0	1.0
Q3	24.0	1.0	28.0	2.0	26.0	3.0
Maximum	48	14	59	14	63	31

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（2/57）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	22.5	-0.7	25.6	1.4	23.0	0.8
SD	6.50	4.27	9.91	7.67	6.08	4.06
Minimum	13	-14	15	-15	11	-10
Q1	18.0	-3.0	21.0	-1.0	19.0	-1.0
Median	21.0	-1.0	23.0	0.0	22.0	0.0
Q3	26.0	1.0	28.0	3.0	26.0	3.0
Maximum	65	23	99	72	51	16
Week 14						
N	128	128	120	120	112	112
Mean	23.0	-0.4	24.9	0.6	22.6	0.4
SD	8.50	5.80	7.81	4.95	5.46	4.57
Minimum	14	-14	14	-11	12	-19
Q1	19.0	-3.0	20.0	-2.0	19.0	-2.0
Median	21.0	-1.0	23.0	0.0	22.0	0.0
Q3	25.0	1.0	27.5	3.0	25.0	3.0
Maximum	73	33	59	19	44	16

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（3/57）

Laboratory Test: AST (GOT) (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	108	108	108	108
Mean	23.0	-0.6	24.1	-0.3	21.9	-0.3
SD	8.55	5.66	7.68	6.00	6.03	5.40
Minimum	13	-15	14	-18	12	-24
Q1	18.0	-3.0	20.0	-3.0	18.0	-3.0
Median	21.0	-1.0	22.0	0.0	21.0	0.0
Q3	25.0	1.0	26.0	2.0	24.0	3.0
Maximum	97	44	62	39	54	23
Week 26						
N	120	120	105	105	105	105
Mean	22.8	-0.8	24.0	-0.3	22.7	0.5
SD	7.39	5.90	5.70	5.13	7.57	6.60
Minimum	14	-13	14	-18	11	-25
Q1	18.0	-3.0	20.0	-3.0	18.0	-2.0
Median	21.0	-1.0	23.0	0.0	22.0	0.0
Q3	25.0	1.0	27.0	3.0	24.0	2.0
Maximum	66	45	45	13	78	47

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（4/57）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	13.3		13.6		12.3	
SD	7.92		8.68		9.85	
Minimum	4		3		3	
Q1	8.0		7.0		7.0	
Median	11.0		12.0		10.0	
Q3	17.0		18.0		15.0	
Maximum	56		45		82	
Week 3						
N	141	141	133	133	127	127
Mean	13.0	-0.3	14.7	1.0	14.7	2.4
SD	7.97	4.88	9.51	5.46	14.14	9.65
Minimum	3	-20	3	-15	4	-20
Q1	7.0	-2.0	7.0	-2.0	7.0	-1.0
Median	11.0	0.0	12.0	1.0	11.0	1.0
Q3	16.0	2.0	19.0	2.0	17.0	3.0
Maximum	46	19	51	26	109	58

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（5/57）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	13.0	-0.3	15.5	1.8	13.7	1.2
SD	8.07	5.40	11.52	8.84	10.67	5.84
Minimum	4	-26	3	-15	3	-22
Q1	7.0	-3.0	7.0	-1.0	8.0	-1.0
Median	10.0	0.0	12.0	1.0	11.0	1.0
Q3	17.0	2.0	21.0	3.0	17.0	4.0
Maximum	59	17	88	78	93	32
Week 14						
N	129	129	121	121	112	112
Mean	12.8	-0.7	14.7	1.0	12.8	-0.1
SD	8.85	5.90	10.71	7.48	7.72	6.87
Minimum	2	-24	3	-14	4	-35
Q1	7.0	-3.0	8.0	-3.0	7.0	-1.0
Median	11.0	-1.0	12.0	0.0	11.0	0.0
Q3	16.0	2.0	17.0	3.0	15.5	3.0
Maximum	55	31	74	53	47	16

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（6/57）

Laboratory Test: ALT (GPT) (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	13.5	-0.1	14.0	0.1	12.8	-0.4
SD	8.37	5.70	9.54	7.48	8.94	8.89
Minimum	3	-22	3	-13	4	-46
Q1	7.0	-4.0	7.0	-4.0	7.0	-3.0
Median	12.0	0.0	11.0	0.0	11.0	0.0
Q3	18.0	4.0	18.0	2.0	16.5	3.0
Maximum	52	14	55	40	71	41
Week 26						
N	120	120	107	107	105	105
Mean	13.9	0.1	14.3	0.3	12.7	-0.4
SD	9.22	6.05	8.79	7.46	8.38	7.83
Minimum	2	-21	3	-22	3	-46
Q1	7.0	-3.0	8.0	-3.0	7.0	-2.0
Median	11.0	0.0	12.0	0.0	11.0	0.0
Q3	18.0	3.0	19.0	3.0	16.0	2.0
Maximum	52	29	51	34	67	37

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（7/57）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	22.4		25.6		20.7	
SD	17.23		18.81		14.13	
Minimum	6		7		7	
Q1	12.0		14.0		13.0	
Median	17.0		19.0		16.0	
Q3	26.0		31.0		25.0	
Maximum	103		108		94	
Week 3						
N	141	141	133	133	127	127
Mean	22.8	0.5	26.3	0.7	21.8	1.2
SD	19.20	11.82	21.15	12.75	15.52	5.13
Minimum	6	-26	7	-19	6	-11
Q1	13.0	-2.0	14.0	-2.0	13.0	-1.0
Median	17.0	0.0	21.0	0.0	16.0	0.0
Q3	27.0	2.0	30.0	1.0	26.0	2.0
Maximum	147	128	153	138	116	30

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（8/57）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	22.0	-0.4	28.0	2.6	22.5	1.7
SD	16.68	5.86	34.88	27.03	15.96	7.00
Minimum	6	-26	6	-21	7	-16
Q1	12.0	-2.0	14.0	-2.0	14.0	-1.0
Median	16.0	0.0	20.0	0.0	17.0	1.0
Q3	27.0	2.0	33.0	2.0	27.0	3.0
Maximum	111	25	359	291	111	38
Week 14						
N	129	129	121	121	112	112
Mean	24.3	1.4	25.4	-0.1	22.8	1.8
SD	24.00	17.72	20.11	11.84	16.30	9.17
Minimum	3	-36	6	-32	6	-17
Q1	13.0	-3.0	14.0	-3.0	13.0	-2.0
Median	17.0	-1.0	19.0	0.0	17.0	0.5
Q3	27.0	2.0	29.0	2.0	27.0	3.0
Maximum	191	172	142	107	96	48

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（9/57）

Laboratory Test: GGT (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	23.6	0.4	27.3	1.7	22.8	1.6
SD	19.49	10.57	31.27	24.30	16.33	8.28
Minimum	4	-47	5	-35	5	-18
Q1	12.0	-3.0	13.0	-2.0	13.0	-2.0
Median	16.0	-1.0	19.5	0.0	18.0	1.0
Q3	27.0	2.0	30.0	2.0	26.0	3.0
Maximum	128	52	288	237	102	39
Week 26						
N	120	120	107	107	105	105
Mean	23.5	0.0	25.4	-0.3	22.0	0.7
SD	19.41	10.15	19.81	9.26	14.74	7.31
Minimum	5	-44	6	-35	6	-20
Q1	12.0	-3.0	13.0	-3.0	13.0	-3.0
Median	17.0	0.0	19.0	0.0	17.0	0.0
Q3	27.5	3.0	29.0	2.0	27.0	2.0
Maximum	122	38	122	45	80	29

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（10/57）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	251.0		268.0		252.8	
SD	83.22		86.29		83.67	
Minimum	84		117		118	
Q1	197.0		205.0		199.0	
Median	237.0		257.0		243.0	
Q3	294.0		321.0		286.0	
Maximum	557		578		607	
Week 3						
N	141	141	133	133	127	127
Mean	252.0	1.0	265.6	-2.4	253.4	3.7
SD	87.54	34.22	82.77	32.83	79.72	25.42
Minimum	80	-103	124	-199	114	-67
Q1	191.0	-15.0	202.0	-19.0	212.0	-11.0
Median	236.0	-1.0	247.0	0.0	248.0	0.0
Q3	299.0	13.0	323.0	9.0	286.0	19.0
Maximum	637	241	538	104	602	104

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（11/57）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	252.0	1.2	264.5	-2.4	254.4	2.7
SD	87.43	31.84	95.34	52.07	80.77	26.58
Minimum	76	-116	123	-118	112	-85
Q1	191.0	-17.0	197.0	-22.0	200.0	-13.0
Median	233.0	0.0	252.0	-3.0	245.5	3.0
Q3	308.0	14.0	312.0	14.0	289.0	16.0
Maximum	664	183	861	479	652	116
Week 14						
N	129	129	121	121	112	112
Mean	253.9	4.1	267.1	1.1	266.3	12.3
SD	87.49	37.93	82.63	51.29	88.17	36.90
Minimum	81	-120	115	-166	119	-68
Q1	196.0	-15.0	205.0	-17.0	213.0	-13.5
Median	238.0	1.0	257.0	-3.0	254.0	7.0
Q3	298.0	20.0	312.0	15.0	314.5	31.5
Maximum	505	147	501	273	660	127

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（12/57）

Laboratory Test: Alkaline Phosphatase (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	243.9	-2.9	267.2	-1.1	258.0	6.7
SD	79.34	41.37	84.61	43.26	88.56	36.99
Minimum	75	-138	110	-219	107	-92
Q1	188.0	-21.0	207.0	-23.0	202.5	-14.0
Median	233.0	-2.0	253.0	1.0	241.0	3.0
Q3	289.0	15.0	316.0	22.0	298.0	23.0
Maximum	487	156	521	199	680	168
Week 26						
N	120	120	107	107	105	105
Mean	241.6	-4.8	265.1	-1.6	257.9	4.7
SD	78.94	41.12	86.89	42.21	90.96	44.30
Minimum	83	-168	112	-160	95	-119
Q1	190.5	-20.5	202.0	-24.0	205.0	-17.0
Median	230.5	-1.0	253.0	-6.0	248.0	2.0
Q3	283.5	14.0	314.0	17.0	289.0	26.0
Maximum	475	81	544	205	771	164

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（13/57）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	191.1		194.2		189.1	
SD	34.29		36.46		37.82	
Minimum	98		120		63	
Q1	167.0		170.0		163.0	
Median	189.0		192.0		182.0	
Q3	207.0		216.0		215.0	
Maximum	330		295		315	
Week 3						
N	141	141	132	132	127	127
Mean	190.6	-0.5	194.6	0.9	191.8	2.9
SD	33.50	16.01	38.93	17.28	40.10	16.80
Minimum	107	-99	125	-55	60	-37
Q1	169.0	-9.0	171.0	-10.5	164.0	-6.0
Median	189.0	-1.0	189.0	0.5	189.0	2.0
Q3	210.0	9.0	218.5	11.0	215.0	10.0
Maximum	321	64	327	68	317	62

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（14/57）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	189.7	-1.7	193.4	0.2	188.5	-0.6
SD	32.54	17.97	37.86	17.33	36.09	16.34
Minimum	122	-86	124	-37	60	-43
Q1	166.0	-11.0	165.0	-11.0	167.0	-10.0
Median	187.0	-2.0	188.0	-1.0	182.0	1.0
Q3	212.0	9.0	217.0	11.0	206.0	7.0
Maximum	342	59	301	59	320	58
Week 14						
N	128	128	120	120	112	112
Mean	190.8	-0.3	196.1	3.0	190.0	2.1
SD	36.02	19.97	42.27	26.54	38.99	20.37
Minimum	130	-97	124	-57	52	-37
Q1	165.0	-9.0	168.0	-10.5	164.0	-10.5
Median	186.5	-1.0	190.5	0.0	183.5	1.0
Q3	216.0	11.0	220.5	12.5	210.0	11.5
Maximum	315	67	359	156	317	56

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（15/57）

Laboratory Test: LDH (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	108	108	108	108
Mean	191.5	1.2	189.8	-1.8	188.0	1.2
SD	39.64	24.58	37.09	18.15	40.91	24.50
Minimum	116	-112	127	-66	52	-58
Q1	161.0	-10.0	160.5	-14.0	162.5	-12.0
Median	185.0	2.0	192.5	0.0	181.5	1.0
Q3	208.0	12.0	209.0	9.5	206.0	12.5
Maximum	313	118	335	79	379	110
Week 26						
N	120	120	105	105	105	105
Mean	191.9	2.3	196.4	4.0	189.7	4.0
SD	37.15	23.63	45.00	28.55	43.57	27.43
Minimum	115	-110	126	-46	57	-49
Q1	166.0	-9.0	169.0	-12.0	162.0	-12.0
Median	186.0	2.0	189.0	2.0	179.0	2.0
Q3	220.5	16.5	216.0	14.0	211.0	14.0
Maximum	291	70	429	173	352	150

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（16/57）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	4.33		4.34		4.31	
SD	0.209		0.216		0.254	
Minimum	3.8		3.5		3.1	
Q1	4.20		4.20		4.10	
Median	4.30		4.40		4.30	
Q3	4.50		4.50		4.50	
Maximum	4.8		4.8		4.8	
Week 3						
N	141	141	133	133	127	127
Mean	4.31	-0.01	4.32	-0.02	4.30	-0.02
SD	0.251	0.164	0.214	0.165	0.232	0.194
Minimum	3.6	-0.4	3.7	-0.4	3.6	-0.9
Q1	4.20	-0.10	4.20	-0.10	4.20	-0.10
Median	4.30	0.00	4.30	0.00	4.30	0.00
Q3	4.50	0.10	4.50	0.10	4.50	0.10
Maximum	5.1	0.5	5.1	0.4	4.8	0.5

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（17/57）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	4.29	-0.04	4.33	-0.01	4.31	0.00
SD	0.237	0.177	0.232	0.171	0.228	0.194
Minimum	3.7	-0.8	3.6	-0.5	3.5	-0.5
Q1	4.10	-0.10	4.20	-0.10	4.20	-0.20
Median	4.30	0.00	4.30	0.00	4.30	0.00
Q3	4.40	0.10	4.50	0.10	4.50	0.10
Maximum	4.9	0.4	4.8	0.4	4.9	0.6
Week 14						
N	129	129	121	121	112	112
Mean	4.31	-0.02	4.32	-0.03	4.27	-0.04
SD	0.250	0.198	0.228	0.175	0.230	0.176
Minimum	3.8	-0.6	3.6	-0.6	3.8	-0.5
Q1	4.10	-0.10	4.10	-0.20	4.10	-0.20
Median	4.30	0.00	4.30	0.00	4.30	0.00
Q3	4.50	0.10	4.50	0.10	4.45	0.10
Maximum	4.9	0.6	4.8	0.4	4.9	0.3

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（18/57）

Laboratory Test: Albumin (g/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	4.29	-0.05	4.29	-0.07	4.24	-0.07
SD	0.225	0.185	0.251	0.201	0.230	0.199
Minimum	3.6	-0.6	3.6	-0.5	3.7	-0.6
Q1	4.10	-0.20	4.20	-0.20	4.10	-0.20
Median	4.30	0.00	4.30	-0.10	4.30	-0.10
Q3	4.50	0.10	4.50	0.10	4.40	0.10
Maximum	4.9	0.5	4.9	0.5	4.7	0.4
Week 26						
N	120	120	107	107	105	105
Mean	4.29	-0.05	4.27	-0.08	4.28	-0.03
SD	0.226	0.179	0.247	0.205	0.214	0.175
Minimum	3.7	-0.6	3.3	-0.6	3.8	-0.5
Q1	4.10	-0.20	4.10	-0.20	4.10	-0.20
Median	4.30	-0.10	4.30	-0.10	4.30	0.00
Q3	4.45	0.10	4.40	0.00	4.40	0.10
Maximum	4.9	0.4	4.9	0.5	4.9	0.5

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（19/57）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	6.92		7.03		6.88	
SD	0.381		0.471		0.414	
Minimum	5.8		5.5		5.5	
Q1	6.70		6.70		6.70	
Median	6.90		7.00		6.90	
Q3	7.10		7.30		7.10	
Maximum	7.9		8.0		8.0	
Week 3						
N	141	141	133	133	127	127
Mean	6.92	0.00	7.02	-0.01	6.85	-0.04
SD	0.400	0.244	0.448	0.265	0.385	0.313
Minimum	5.8	-0.6	5.9	-0.8	5.8	-0.9
Q1	6.70	-0.20	6.80	-0.20	6.60	-0.30
Median	6.90	0.00	7.00	0.00	6.80	0.00
Q3	7.10	0.20	7.20	0.10	7.00	0.10
Maximum	8.1	0.6	8.2	0.7	8.1	1.0

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（20/57）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	6.89	-0.03	7.01	-0.03	6.89	0.00
SD	0.413	0.253	0.466	0.288	0.402	0.257
Minimum	5.9	-0.8	5.7	-0.8	5.9	-0.6
Q1	6.60	-0.20	6.70	-0.20	6.60	-0.20
Median	6.90	0.00	7.00	0.00	6.90	0.00
Q3	7.20	0.10	7.30	0.20	7.20	0.20
Maximum	7.9	0.6	8.3	0.6	7.9	0.6
Week 14						
N	129	129	121	121	112	112
Mean	6.91	-0.02	6.99	-0.05	6.84	-0.05
SD	0.411	0.268	0.451	0.309	0.386	0.279
Minimum	5.9	-0.7	5.6	-1.2	5.8	-0.8
Q1	6.60	-0.20	6.70	-0.30	6.60	-0.20
Median	7.00	0.00	7.00	0.00	6.80	0.00
Q3	7.20	0.10	7.30	0.10	7.10	0.10
Maximum	7.8	0.7	8.4	0.7	7.7	0.7

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（21/57）

Laboratory Test: Total Protein (g/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	6.89	-0.05	6.98	-0.08	6.81	-0.08
SD	0.373	0.284	0.460	0.333	0.410	0.302
Minimum	6.0	-0.7	5.6	-0.8	5.8	-0.8
Q1	6.60	-0.20	6.70	-0.30	6.60	-0.30
Median	6.90	-0.10	7.00	-0.10	6.80	-0.10
Q3	7.10	0.10	7.20	0.10	7.10	0.10
Maximum	7.8	0.9	8.6	1.0	7.7	0.7
Week 26						
N	120	120	107	107	105	105
Mean	6.89	-0.05	6.98	-0.09	6.86	-0.03
SD	0.383	0.260	0.463	0.305	0.417	0.313
Minimum	6.1	-0.7	5.7	-1.0	5.7	-0.9
Q1	6.60	-0.25	6.70	-0.30	6.60	-0.20
Median	6.90	0.00	6.90	-0.10	6.90	0.00
Q3	7.15	0.10	7.30	0.10	7.10	0.20
Maximum	7.6	0.5	8.1	0.7	7.9	0.7

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（22/57）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	0.75		0.75		0.79	
SD	0.282		0.286		0.279	
Minimum	0.4		0.3		0.3	
Q1	0.60		0.60		0.60	
Median	0.70		0.70		0.70	
Q3	0.90		0.80		0.90	
Maximum	1.8		1.9		2.0	
Week 3						
N	141	141	133	133	127	127
Mean	0.77	0.01	0.74	-0.01	0.78	-0.01
SD	0.289	0.198	0.322	0.202	0.255	0.193
Minimum	0.3	-0.4	0.3	-0.6	0.3	-0.6
Q1	0.60	-0.10	0.60	-0.10	0.60	-0.10
Median	0.70	0.00	0.70	0.00	0.70	0.00
Q3	0.90	0.10	0.80	0.10	1.00	0.10
Maximum	2.0	0.9	3.2	1.3	1.6	0.5

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（23/57）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	0.72	-0.03	0.71	-0.04	0.80	0.00
SD	0.281	0.188	0.255	0.196	0.288	0.214
Minimum	0.3	-0.7	0.4	-0.8	0.2	-0.6
Q1	0.60	-0.20	0.50	-0.10	0.60	-0.10
Median	0.70	0.00	0.70	0.00	0.75	0.00
Q3	0.80	0.10	0.80	0.10	0.90	0.10
Maximum	1.8	0.6	2.3	0.4	2.1	0.8
Week 14						
N	129	129	121	121	112	112
Mean	0.74	-0.02	0.72	-0.03	0.76	-0.03
SD	0.278	0.211	0.249	0.207	0.279	0.207
Minimum	0.3	-0.6	0.4	-0.8	0.2	-0.8
Q1	0.50	-0.10	0.60	-0.10	0.60	-0.10
Median	0.70	0.00	0.70	0.00	0.70	0.00
Q3	0.90	0.10	0.80	0.10	0.90	0.10
Maximum	1.6	0.7	2.0	0.5	2.0	0.7

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（24/57）

Laboratory Test: Total Bilirubin (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	0.76	0.00	0.72	-0.03	0.74	-0.06
SD	0.278	0.214	0.288	0.202	0.255	0.236
Minimum	0.3	-0.6	0.4	-0.6	0.2	-1.1
Q1	0.60	-0.10	0.50	-0.20	0.60	-0.20
Median	0.70	0.00	0.60	0.00	0.70	0.00
Q3	0.90	0.10	0.80	0.10	0.90	0.10
Maximum	1.8	0.5	2.0	0.6	1.7	0.6
Week 26						
N	120	120	107	107	105	105
Mean	0.77	0.00	0.72	-0.03	0.80	0.00
SD	0.268	0.253	0.322	0.205	0.279	0.215
Minimum	0.3	-0.7	0.3	-0.6	0.2	-0.7
Q1	0.60	-0.10	0.50	-0.10	0.60	-0.10
Median	0.70	0.00	0.70	0.00	0.80	0.00
Q3	0.90	0.10	0.80	0.10	0.90	0.10
Maximum	1.7	0.9	1.9	0.7	1.8	0.5

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（25/57）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	192.7		197.6		197.8	
SD	32.40		33.18		31.00	
Minimum	129		107		126	
Q1	171.0		175.0		176.0	
Median	189.0		194.0		198.0	
Q3	215.0		216.0		216.0	
Maximum	339		306		277	
Week 3						
N	141	141	133	133	127	127
Mean	193.2	0.5	197.2	-0.3	198.2	0.0
SD	32.28	15.07	32.28	14.85	30.99	15.46
Minimum	135	-47	121	-30	133	-39
Q1	170.0	-9.0	174.0	-11.0	175.0	-12.0
Median	191.0	1.0	196.0	-1.0	195.0	-2.0
Q3	212.0	11.0	220.0	10.0	222.0	10.0
Maximum	292	33	286	37	283	48

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（26/57）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	192.5	0.2	195.9	-1.8	198.4	0.6
SD	31.69	17.55	34.82	15.99	30.87	16.53
Minimum	131	-45	118	-41	117	-44
Q1	170.0	-11.0	172.0	-12.0	176.0	-9.0
Median	189.0	0.0	195.0	-2.0	201.0	-1.0
Q3	213.0	10.0	220.0	8.0	222.0	12.0
Maximum	301	52	295	46	275	35
Week 14						
N	129	129	121	121	112	112
Mean	190.7	-1.8	196.5	-1.9	194.0	-3.4
SD	31.68	15.91	33.97	20.85	30.95	15.77
Minimum	128	-51	111	-48	123	-47
Q1	166.0	-11.0	176.0	-14.0	169.0	-12.0
Median	188.0	-2.0	197.0	-3.0	192.5	-4.0
Q3	210.0	8.0	217.0	10.0	216.0	7.5
Maximum	301	51	299	65	257	39

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（27/57）

Laboratory Test: Total Cholesterol (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	190.2	-1.5	195.2	-3.5	193.2	-3.2
SD	29.88	17.96	34.94	25.21	30.48	18.96
Minimum	124	-99	119	-64	131	-78
Q1	170.0	-10.0	170.0	-18.0	172.0	-12.0
Median	190.0	-1.0	193.0	-6.5	191.0	-1.5
Q3	208.0	10.0	216.0	9.0	216.0	10.0
Maximum	273	44	295	90	269	64
Week 26						
N	120	120	107	107	105	105
Mean	188.8	-3.2	191.4	-7.3	194.5	-2.3
SD	28.47	18.69	33.30	23.02	32.90	20.26
Minimum	125	-74	115	-64	122	-64
Q1	168.5	-14.0	169.0	-22.0	171.0	-15.0
Median	188.0	-4.0	191.0	-6.0	195.0	-2.0
Q3	206.0	10.5	210.0	9.0	213.0	11.0
Maximum	263	45	289	84	280	59

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（28/57）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	87.8		83.5		87.7	
SD	65.84		43.02		49.75	
Minimum	33		26		30	
Q1	57.0		54.0		56.0	
Median	74.0		71.0		72.0	
Q3	96.0		96.0		98.0	
Maximum	713		230		272	
Week 3						
N	141	141	133	133	127	127
Mean	87.6	-0.2	86.1	2.6	95.1	7.0
SD	52.31	36.49	41.97	34.47	61.04	38.41
Minimum	29	-279	32	-166	27	-107
Q1	59.0	-13.0	55.0	-12.0	55.0	-10.0
Median	71.0	1.0	74.0	4.0	79.0	3.0
Q3	101.0	16.0	108.0	19.0	109.0	20.0
Maximum	434	83	239	100	412	162

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（29/57）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	86.8	-0.8	86.3	3.3	93.6	4.5
SD	44.73	52.82	45.52	34.10	58.59	45.80
Minimum	28	-514	26	-180	30	-182
Q1	56.0	-16.0	54.0	-10.0	56.0	-13.0
Median	76.0	1.0	73.0	4.0	76.0	0.0
Q3	102.0	18.0	102.0	17.0	110.0	13.0
Maximum	258	85	267	107	441	191
Week 14						
N	129	129	121	121	112	112
Mean	83.4	-4.3	82.8	-1.6	90.2	1.8
SD	45.85	47.72	36.55	32.45	57.02	42.88
Minimum	24	-422	30	-150	27	-153
Q1	52.0	-15.0	60.0	-17.0	57.5	-10.5
Median	74.0	-3.0	74.0	1.0	73.5	3.0
Q3	98.0	13.0	104.0	15.0	104.0	18.0
Maximum	291	95	274	110	459	209

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（30/57）

Laboratory Test: Triglycerides (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	88.9	0.3	82.5	-3.0	91.9	3.5
SD	54.01	40.01	36.94	28.36	62.58	42.24
Minimum	28	-259	34	-120	26	-122
Q1	57.0	-16.0	57.0	-16.0	58.5	-15.5
Median	73.0	1.0	74.5	1.5	73.5	1.0
Q3	104.0	17.0	100.0	10.0	96.5	18.5
Maximum	454	145	262	84	473	216
Week 26						
N	120	120	107	107	105	105
Mean	92.0	3.1	85.7	-0.6	96.0	7.1
SD	59.13	43.59	40.56	30.87	76.60	53.67
Minimum	28	-255	34	-131	36	-98
Q1	57.0	-16.5	58.0	-17.0	57.0	-11.0
Median	73.5	-2.0	72.0	5.0	73.0	3.0
Q3	116.5	21.5	101.0	17.0	102.0	20.0
Maximum	458	158	244	62	629	415

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（31/57）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	0.698		0.718		0.713	
SD	0.1653		0.1736		0.1920	
Minimum	0.34		0.42		0.43	
Q1	0.590		0.590		0.580	
Median	0.690		0.660		0.660	
Q3	0.800		0.830		0.840	
Maximum	1.32		1.37		1.62	
Week 3						
N	141	141	133	133	127	127
Mean	0.696	-0.002	0.721	0.003	0.716	0.001
SD	0.1579	0.0510	0.1720	0.0549	0.1925	0.0596
Minimum	0.37	-0.18	0.41	-0.13	0.36	-0.16
Q1	0.590	-0.030	0.590	-0.030	0.570	-0.050
Median	0.690	0.000	0.690	0.000	0.670	0.000
Q3	0.800	0.030	0.820	0.040	0.840	0.040
Maximum	1.19	0.11	1.39	0.21	1.46	0.23

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（32/57）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	0.690	-0.007	0.714	-0.004	0.719	0.003
SD	0.1573	0.0513	0.1737	0.0589	0.1947	0.0634
Minimum	0.33	-0.20	0.43	-0.14	0.40	-0.19
Q1	0.580	-0.040	0.580	-0.040	0.590	-0.040
Median	0.700	0.000	0.680	-0.010	0.665	0.000
Q3	0.800	0.020	0.810	0.030	0.840	0.040
Maximum	1.23	0.10	1.35	0.19	1.51	0.20
Week 14						
N	129	129	121	121	112	112
Mean	0.688	-0.003	0.715	-0.009	0.726	0.007
SD	0.1563	0.0547	0.1824	0.0641	0.2108	0.0719
Minimum	0.37	-0.23	0.39	-0.16	0.39	-0.16
Q1	0.580	-0.040	0.590	-0.050	0.575	-0.040
Median	0.680	0.000	0.680	-0.010	0.660	0.000
Q3	0.800	0.030	0.810	0.030	0.880	0.050
Maximum	1.30	0.13	1.41	0.25	1.52	0.35

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（33/57）

Laboratory Test: Creatinine (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	0.701	0.007	0.732	0.003	0.725	0.006
SD	0.1810	0.0846	0.1889	0.1039	0.2176	0.0755
Minimum	0.38	-0.17	0.40	-0.15	0.38	-0.18
Q1	0.570	-0.040	0.600	-0.040	0.560	-0.050
Median	0.680	0.000	0.705	-0.010	0.695	0.000
Q3	0.810	0.040	0.830	0.030	0.865	0.050
Maximum	1.50	0.61	1.49	0.80	1.59	0.32
Week 26						
N	120	120	107	107	105	105
Mean	0.709	0.011	0.724	-0.005	0.738	0.016
SD	0.1856	0.0852	0.1769	0.0761	0.2082	0.0663
Minimum	0.36	-0.21	0.42	-0.15	0.37	-0.21
Q1	0.600	-0.030	0.590	-0.060	0.580	-0.030
Median	0.685	0.010	0.710	-0.010	0.700	0.020
Q3	0.820	0.040	0.830	0.030	0.860	0.060
Maximum	1.51	0.63	1.46	0.27	1.48	0.16

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（34/57）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	17.0		16.9		17.1	
SD	4.50		4.58		4.67	
Minimum	9		9		9	
Q1	14.0		14.0		14.0	
Median	16.0		17.0		16.0	
Q3	19.0		19.0		20.0	
Maximum	31		30		34	
Week 3						
N	141	141	133	133	127	127
Mean	17.2	0.2	17.1	0.1	17.3	0.2
SD	4.84	3.72	4.43	3.04	4.43	3.90
Minimum	10	-16	9	-8	9	-21
Q1	14.0	-2.0	14.0	-2.0	14.0	-2.0
Median	16.0	1.0	16.0	0.0	16.0	0.0
Q3	20.0	2.0	19.0	2.0	20.0	3.0
Maximum	36	10	29	8	33	12

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（35/57）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	16.9	-0.1	17.0	0.1	17.1	0.1
SD	4.29	3.64	5.11	4.25	4.67	3.70
Minimum	8	-14	7	-10	8	-9
Q1	14.0	-2.0	14.0	-2.0	14.0	-2.0
Median	16.0	0.0	16.0	0.0	16.0	0.0
Q3	19.0	2.0	19.0	3.0	19.0	2.0
Maximum	30	10	46	16	36	17
Week 14						
N	129	129	121	121	112	112
Mean	17.2	0.3	17.9	0.8	17.8	0.8
SD	3.91	3.64	5.20	3.96	5.37	3.76
Minimum	8	-11	9	-9	10	-9
Q1	14.0	-2.0	14.0	-2.0	14.0	-1.0
Median	17.0	1.0	17.0	0.0	17.0	0.5
Q3	20.0	3.0	21.0	3.0	20.5	2.5
Maximum	31	9	41	11	43	13

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（36/57）

Laboratory Test: Blood Urea Nitrogen (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	17.6	0.6	17.1	0.1	17.9	0.9
SD	5.10	4.41	4.70	3.63	5.19	3.35
Minimum	9	-9	8	-11	10	-7
Q1	14.0	-2.0	14.0	-3.0	13.0	-1.0
Median	17.0	1.0	17.0	0.0	18.0	1.0
Q3	19.0	3.0	20.0	2.0	21.0	3.0
Maximum	40	21	36	9	38	13
Week 26						
N	120	120	107	107	105	105
Mean	17.6	0.8	17.3	0.4	18.0	1.0
SD	5.58	4.58	4.84	4.19	5.33	3.52
Minimum	10	-9	10	-11	9	-9
Q1	14.0	-1.5	14.0	-2.0	14.0	-1.0
Median	16.5	1.0	17.0	0.0	18.0	1.0
Q3	19.0	3.0	20.0	2.0	21.0	3.0
Maximum	54	26	40	21	35	15

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（37/57）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	4.29		4.46		4.21	
SD	1.295		1.272		1.094	
Minimum	0.8		1.7		0.6	
Q1	3.40		3.60		3.40	
Median	4.20		4.30		4.20	
Q3	5.20		5.20		4.90	
Maximum	8.7		8.2		6.9	
Week 3						
N	141	141	133	133	127	127
Mean	4.24	-0.05	4.44	-0.02	4.24	0.02
SD	1.275	0.539	1.236	0.482	1.123	0.500
Minimum	0.7	-2.0	1.6	-1.4	0.6	-2.0
Q1	3.30	-0.40	3.60	-0.30	3.40	-0.30
Median	4.10	0.00	4.20	0.00	4.20	0.00
Q3	4.90	0.20	5.20	0.30	5.00	0.40
Maximum	8.7	1.8	8.0	1.6	7.2	1.1

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（38/57）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	4.25	-0.05	4.36	-0.10	4.30	0.06
SD	1.235	0.483	1.244	0.464	1.108	0.570
Minimum	0.7	-1.8	1.7	-1.4	0.6	-2.0
Q1	3.40	-0.40	3.50	-0.40	3.50	-0.20
Median	4.20	0.00	4.20	-0.10	4.25	0.10
Q3	5.20	0.30	5.10	0.20	5.10	0.40
Maximum	8.5	1.6	7.6	1.3	7.2	1.6
Week 14						
N	129	129	121	121	112	112
Mean	4.28	0.00	4.40	-0.05	4.26	0.03
SD	1.238	0.543	1.245	0.520	1.084	0.557
Minimum	0.9	-2.3	1.5	-1.0	0.5	-1.8
Q1	3.40	-0.30	3.60	-0.40	3.55	-0.30
Median	4.20	0.00	4.20	-0.10	4.15	0.00
Q3	5.00	0.40	5.30	0.20	5.00	0.40
Maximum	7.7	1.7	7.7	1.8	6.9	1.4

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（39/57）

Laboratory Test: Uric Acid (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	4.28	-0.03	4.33	-0.09	4.25	0.02
SD	1.337	0.689	1.250	0.578	1.247	0.622
Minimum	0.8	-2.7	1.4	-1.5	0.6	-1.8
Q1	3.40	-0.40	3.40	-0.50	3.40	-0.30
Median	4.20	0.00	4.30	-0.10	4.10	0.00
Q3	5.00	0.30	5.00	0.20	5.05	0.40
Maximum	9.0	3.0	7.8	1.6	9.0	2.5
Week 26						
N	120	120	107	107	105	105
Mean	4.32	-0.01	4.39	-0.06	4.26	0.03
SD	1.376	0.687	1.229	0.622	1.162	0.536
Minimum	0.7	-2.6	1.3	-1.6	0.6	-1.5
Q1	3.40	-0.40	3.50	-0.40	3.50	-0.20
Median	4.20	0.00	4.20	-0.10	4.20	0.00
Q3	5.15	0.30	5.20	0.30	5.00	0.40
Maximum	9.7	3.3	7.3	2.4	7.1	1.2

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（40/57）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	131.6		140.0		137.1	
SD	92.00		75.92		83.37	
Minimum	44		38		40	
Q1	83.0		87.0		88.0	
Median	110.0		122.0		119.0	
Q3	139.0		167.0		162.0	
Maximum	885		512		611	
Week 3						
N	141	141	133	133	127	127
Mean	129.4	-2.2	147.0	7.1	136.0	-1.0
SD	89.17	73.75	75.76	71.61	81.52	79.20
Minimum	41	-295	33	-289	33	-537
Q1	82.0	-14.0	91.0	-9.0	87.0	-16.0
Median	104.0	0.0	126.0	3.0	117.0	1.0
Q3	137.0	14.0	187.0	26.0	167.0	25.0
Maximum	720	401	400	341	580	388

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（41/57）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	128.7	-3.6	147.8	7.1	130.8	-7.4
SD	75.32	83.58	91.33	85.53	64.71	70.36
Minimum	46	-404	34	-320	35	-535
Q1	83.0	-18.0	84.0	-18.0	86.0	-18.0
Median	113.0	-2.0	121.0	1.0	115.0	-1.0
Q3	144.0	16.0	179.0	28.0	155.0	16.0
Maximum	534	448	593	449	441	169
Week 14						
N	129	129	121	121	112	112
Mean	123.4	-3.6	142.6	2.3	137.0	1.2
SD	73.71	78.50	86.25	74.52	89.00	97.54
Minimum	39	-423	33	-256	30	-541
Q1	85.0	-13.0	89.0	-20.0	86.0	-21.0
Median	103.0	-1.0	125.0	-1.0	110.5	-1.0
Q3	136.0	18.0	169.0	18.0	153.0	24.0
Maximum	640	539	596	435	685	586

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（42/57）

Laboratory Test: CK (CPK) (U/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	123.0	-3.3	148.0	11.3	129.8	-7.1
SD	67.56	59.07	195.55	199.81	69.69	82.88
Minimum	39	-298	47	-281	29	-517
Q1	83.0	-16.0	90.0	-26.0	85.5	-33.5
Median	110.0	0.0	114.0	3.5	112.0	-0.5
Q3	139.0	19.0	151.0	23.0	150.0	22.5
Maximum	592	182	2076	1995	466	347
Week 26						
N	120	120	107	107	105	105
Mean	126.9	0.4	138.3	1.0	140.7	4.6
SD	76.71	63.11	68.89	68.35	94.02	98.81
Minimum	44	-269	42	-262	40	-541
Q1	82.5	-17.0	97.0	-24.0	82.0	-30.0
Median	110.5	1.0	110.0	1.0	114.0	-1.0
Q3	152.5	25.5	166.0	26.0	148.0	21.0
Maximum	651	244	397	229	524	375

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（43/57）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	141.1		140.8		140.6	
SD	2.05		2.18		2.53	
Minimum	136		131		127	
Q1	140.0		140.0		140.0	
Median	141.0		141.0		141.0	
Q3	142.0		142.0		142.0	
Maximum	146		148		145	
Week 3						
N	141	141	133	133	127	127
Mean	140.8	-0.3	140.6	-0.2	140.4	-0.2
SD	1.88	1.71	2.31	1.64	2.19	1.88
Minimum	136	-4	131	-4	131	-4
Q1	140.0	-2.0	140.0	-1.0	140.0	-1.0
Median	141.0	0.0	141.0	0.0	141.0	0.0
Q3	142.0	1.0	142.0	1.0	142.0	1.0
Maximum	144	4	145	4	144	6

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（44/57）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	140.7	-0.4	140.4	-0.4	140.3	-0.4
SD	1.91	1.77	2.28	1.77	2.17	2.12
Minimum	134	-5	131	-5	134	-5
Q1	140.0	-2.0	139.0	-2.0	139.0	-2.0
Median	141.0	0.0	141.0	0.0	140.0	-0.5
Q3	142.0	1.0	142.0	1.0	142.0	1.0
Maximum	145	5	145	5	145	8
Week 14						
N	129	129	121	121	112	112
Mean	140.8	-0.4	140.4	-0.4	140.5	-0.3
SD	1.90	1.73	2.35	1.65	1.90	2.08
Minimum	135	-6	129	-5	134	-5
Q1	140.0	-1.0	139.0	-1.0	139.0	-1.0
Median	141.0	0.0	140.0	0.0	141.0	0.0
Q3	142.0	1.0	142.0	1.0	142.0	1.0
Maximum	146	4	145	4	145	7

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（45/57）

Laboratory Test: Sodium (mEq/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	141.2	0.0	140.4	-0.4	140.5	-0.3
SD	1.85	1.86	2.37	1.81	2.27	2.11
Minimum	135	-5	129	-5	131	-6
Q1	140.0	-1.0	139.0	-2.0	139.0	-1.5
Median	141.0	0.0	141.0	-1.0	141.0	0.0
Q3	142.0	1.0	142.0	1.0	142.0	1.0
Maximum	146	6	144	5	145	5
Week 26						
N	120	120	107	107	105	105
Mean	141.0	-0.2	140.3	-0.5	140.3	-0.4
SD	1.80	1.85	2.46	1.80	2.35	2.00
Minimum	137	-6	127	-6	132	-6
Q1	140.0	-1.0	139.0	-2.0	139.0	-2.0
Median	141.0	0.0	141.0	-1.0	141.0	-1.0
Q3	142.0	1.0	142.0	1.0	142.0	1.0
Maximum	145	4	145	3	146	5

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（46/57）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline						
N	141		133		129	
Mean	4.12		4.14		4.08	
SD	0.338		0.369		0.327	
Minimum	3.1		2.9		3.2	
Q1	3.90		3.90		3.90	
Median	4.10		4.10		4.00	
Q3	4.40		4.30		4.20	
Maximum	5.1		5.1		5.0	
Week 3						
N	141	141	132	132	127	127
Mean	4.10	-0.02	4.18	0.03	4.11	0.03
SD	0.304	0.285	0.339	0.273	0.333	0.266
Minimum	3.4	-1.1	3.2	-1.0	3.2	-0.9
Q1	3.90	-0.20	4.00	-0.10	3.90	-0.10
Median	4.10	0.00	4.10	0.00	4.10	0.00
Q3	4.30	0.20	4.35	0.20	4.30	0.20
Maximum	5.0	0.7	5.4	0.7	5.5	0.8

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（47/57）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	4.10	-0.02	4.16	0.03	4.13	0.05
SD	0.299	0.290	0.347	0.298	0.333	0.306
Minimum	3.3	-0.9	3.1	-0.7	3.2	-0.9
Q1	3.90	-0.20	3.90	-0.10	3.90	-0.10
Median	4.10	0.00	4.20	0.00	4.10	0.00
Q3	4.30	0.20	4.30	0.20	4.30	0.20
Maximum	5.0	0.6	5.2	0.8	5.3	0.8
Week 14						
N	128	128	120	120	112	112
Mean	4.13	0.01	4.19	0.04	4.16	0.08
SD	0.308	0.286	0.322	0.289	0.329	0.283
Minimum	3.2	-1.1	3.2	-0.7	3.5	-1.0
Q1	4.00	-0.10	4.00	-0.10	4.00	-0.10
Median	4.10	0.00	4.20	0.00	4.10	0.10
Q3	4.30	0.20	4.40	0.20	4.30	0.20
Maximum	5.5	1.0	5.3	0.8	5.2	0.7

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（48/57）

Laboratory Test: Potassium (mEq/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	108	108	108	108
Mean	4.14	0.01	4.21	0.07	4.16	0.09
SD	0.320	0.325	0.317	0.274	0.358	0.280
Minimum	3.4	-1.2	3.4	-0.9	3.3	-0.6
Q1	3.90	-0.20	4.00	-0.10	4.00	-0.10
Median	4.10	0.00	4.20	0.10	4.10	0.10
Q3	4.30	0.20	4.40	0.20	4.30	0.25
Maximum	5.4	1.2	5.1	0.8	5.5	0.8
Week 26						
N	120	120	105	105	105	105
Mean	4.14	0.02	4.19	0.05	4.16	0.09
SD	0.305	0.325	0.286	0.294	0.343	0.281
Minimum	3.4	-1.3	3.5	-0.8	3.5	-0.7
Q1	3.95	-0.20	4.00	-0.10	3.90	-0.10
Median	4.10	0.00	4.20	0.10	4.10	0.10
Q3	4.30	0.20	4.40	0.20	4.40	0.20
Maximum	5.3	0.8	4.8	1.1	5.2	1.0

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（49/57）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	103.9		103.6		103.7	
SD	2.44		2.73		2.76	
Minimum	94		94		93	
Q1	103.0		102.0		102.0	
Median	104.0		104.0		104.0	
Q3	106.0		105.0		105.0	
Maximum	110		110		110	
Week 3						
N	141	141	133	133	127	127
Mean	103.5	-0.4	103.5	-0.1	103.4	-0.3
SD	2.33	1.70	2.81	1.84	2.47	2.00
Minimum	98	-5	93	-5	95	-5
Q1	102.0	-1.0	102.0	-1.0	102.0	-2.0
Median	103.0	0.0	104.0	0.0	103.0	0.0
Q3	105.0	1.0	105.0	1.0	105.0	1.0
Maximum	110	4	109	4	110	7

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（50/57）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	103.8	-0.2	103.2	-0.4	103.2	-0.6
SD	2.20	1.74	2.73	1.80	2.32	1.89
Minimum	97	-5	95	-5	98	-6
Q1	102.0	-1.0	102.0	-1.0	102.0	-2.0
Median	104.0	0.0	103.0	0.0	103.0	0.0
Q3	105.0	1.0	105.0	1.0	105.0	1.0
Maximum	109	5	110	6	109	5
Week 14						
N	129	129	121	121	112	112
Mean	103.6	-0.4	103.4	-0.2	103.6	-0.2
SD	2.37	1.98	2.48	1.81	2.28	1.98
Minimum	96	-6	97	-5	96	-5
Q1	102.0	-2.0	102.0	-1.0	102.0	-2.0
Median	104.0	0.0	104.0	0.0	104.0	0.0
Q3	105.0	1.0	105.0	1.0	105.0	1.0
Maximum	109	4	109	4	109	6

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（51/57）

Laboratory Test: Chloride (mEq/L)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	104.2	0.3	103.8	0.2	103.8	0.0
SD	2.53	2.50	2.75	2.24	2.67	2.40
Minimum	98	-5	93	-6	93	-7
Q1	103.0	-2.0	102.0	-1.0	102.0	-1.0
Median	104.0	0.0	104.0	0.0	104.0	0.0
Q3	106.0	2.0	106.0	2.0	105.5	2.0
Maximum	111	10	109	7	111	5
Week 26						
N	120	120	107	107	105	105
Mean	104.0	0.2	103.8	0.2	103.5	-0.3
SD	2.43	2.38	2.68	2.46	2.71	2.30
Minimum	98	-5	94	-7	94	-5
Q1	103.0	-2.0	102.0	-1.0	102.0	-2.0
Median	104.0	0.0	104.0	0.0	104.0	0.0
Q3	106.0	2.0	105.0	2.0	105.0	1.0
Maximum	112	5	111	6	109	5

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（52/57）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	9.02		9.07		9.01	
SD	0.288		0.312		0.340	
Minimum	8.3		8.4		7.8	
Q1	8.80		8.90		8.80	
Median	9.00		9.00		9.00	
Q3	9.20		9.20		9.20	
Maximum	9.8		10.2		10.2	
Week 3						
N	141	141	133	133	127	127
Mean	9.02	0.01	9.08	0.01	9.00	-0.02
SD	0.315	0.223	0.269	0.237	0.299	0.269
Minimum	8.2	-0.5	8.3	-0.7	8.2	-0.6
Q1	8.80	-0.20	8.90	-0.10	8.80	-0.20
Median	9.00	0.00	9.10	0.00	9.00	0.00
Q3	9.20	0.20	9.30	0.20	9.20	0.20
Maximum	10.1	0.7	9.9	0.8	9.9	0.7

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（53/57）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	8.98	-0.04	9.07	0.01	9.04	0.02
SD	0.313	0.246	0.299	0.232	0.341	0.271
Minimum	8.2	-0.7	8.5	-0.7	8.1	-0.7
Q1	8.80	-0.20	8.90	-0.10	8.80	-0.20
Median	9.00	-0.10	9.10	0.00	9.00	0.00
Q3	9.20	0.10	9.30	0.20	9.30	0.20
Maximum	10.0	0.6	9.9	0.7	9.9	0.6
Week 14						
N	129	129	121	121	112	112
Mean	8.99	-0.03	9.03	-0.04	8.97	-0.06
SD	0.346	0.257	0.337	0.270	0.357	0.268
Minimum	8.2	-0.7	8.2	-0.8	7.9	-0.7
Q1	8.70	-0.20	8.80	-0.20	8.70	-0.20
Median	9.00	-0.10	9.00	-0.10	8.95	-0.10
Q3	9.20	0.10	9.30	0.20	9.20	0.10
Maximum	9.8	0.5	10.0	0.6	10.0	0.8

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（54/57）

Laboratory Test: Calcium (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	8.97	-0.05	8.98	-0.08	8.91	-0.11
SD	0.295	0.258	0.310	0.292	0.332	0.262
Minimum	8.3	-0.8	8.1	-0.8	7.8	-0.8
Q1	8.80	-0.20	8.80	-0.30	8.70	-0.30
Median	9.00	-0.10	8.90	-0.10	8.90	-0.10
Q3	9.20	0.10	9.10	0.10	9.15	0.10
Maximum	9.6	0.6	9.9	0.7	9.8	0.4
Week 26						
N	120	120	107	107	105	105
Mean	8.93	-0.09	8.93	-0.14	8.90	-0.12
SD	0.304	0.239	0.316	0.263	0.309	0.288
Minimum	8.2	-0.6	7.8	-0.9	7.9	-0.7
Q1	8.70	-0.30	8.70	-0.30	8.70	-0.30
Median	8.95	-0.10	8.90	-0.10	8.90	-0.10
Q3	9.10	0.10	9.10	0.00	9.10	0.10
Maximum	9.8	0.6	9.9	0.4	9.7	0.8

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（55/57）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=141) Observed Value at Visit	Placebo (N=141) Change from Baseline	0.5 mg (N=133) Observed Value at Visit	0.5 mg (N=133) Change from Baseline	1 mg (N=129) Observed Value at Visit	1 mg (N=129) Change from Baseline
Baseline						
N	141		133		129	
Mean	3.36		3.33		3.33	
SD	0.478		0.455		0.387	
Minimum	2.3		2.2		2.3	
Q1	3.10		3.00		3.10	
Median	3.30		3.30		3.30	
Q3	3.70		3.60		3.60	
Maximum	4.4		4.5		4.4	
Week 3						
N	141	141	133	133	127	127
Mean	3.42	0.06	3.38	0.05	3.34	0.01
SD	0.438	0.383	0.468	0.323	0.424	0.372
Minimum	2.4	-1.0	2.3	-0.9	2.2	-1.4
Q1	3.10	-0.20	3.10	-0.10	3.10	-0.20
Median	3.50	0.10	3.30	0.00	3.40	0.00
Q3	3.70	0.30	3.70	0.20	3.60	0.20
Maximum	4.7	1.9	4.8	1.0	4.4	0.9

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（56/57）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 6						
N	139	139	127	127	122	122
Mean	3.33	-0.03	3.37	0.03	3.35	0.04
SD	0.452	0.368	0.451	0.308	0.439	0.406
Minimum	1.8	-1.3	2.2	-0.8	1.7	-0.9
Q1	3.00	-0.30	3.10	-0.20	3.10	-0.20
Median	3.40	0.00	3.40	0.00	3.40	0.00
Q3	3.70	0.20	3.70	0.20	3.70	0.30
Maximum	4.4	0.9	4.3	0.7	4.2	1.2
Week 14						
N	129	129	121	121	112	112
Mean	3.42	0.05	3.36	0.02	3.43	0.11
SD	0.479	0.401	0.470	0.326	0.445	0.429
Minimum	2.1	-1.8	2.1	-0.9	2.4	-1.0
Q1	3.10	-0.10	3.10	-0.20	3.10	-0.20
Median	3.40	0.10	3.40	0.00	3.40	0.00
Q3	3.70	0.30	3.70	0.20	3.70	0.40
Maximum	4.4	0.8	4.4	1.0	4.7	1.5

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-67　血液生化学検査の評価時点別変化量（CCT-002 試験）（57/57）

Laboratory Test: Phosphorus (mg/dL)

Visit / Statistics	Placebo (N=141)		0.5 mg (N=133)		1 mg (N=129)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20						
N	123	123	110	110	108	108
Mean	3.40	0.03	3.33	-0.01	3.35	0.03
SD	0.474	0.419	0.421	0.386	0.390	0.361
Minimum	2.3	-1.2	2.4	-1.2	2.2	-0.8
Q1	3.10	-0.20	3.00	-0.30	3.10	-0.20
Median	3.50	0.00	3.30	0.00	3.40	-0.05
Q3	3.70	0.30	3.60	0.20	3.60	0.20
Maximum	4.6	1.1	4.3	1.0	4.4	0.9
Week 26						
N	120	120	107	107	105	105
Mean	3.36	0.00	3.27	-0.07	3.37	0.05
SD	0.403	0.396	0.451	0.365	0.433	0.380
Minimum	2.0	-1.2	2.1	-1.3	2.4	-1.0
Q1	3.10	-0.30	2.90	-0.30	3.10	-0.20
Median	3.40	0.00	3.20	-0.10	3.50	0.10
Q3	3.60	0.30	3.60	0.20	3.60	0.30
Maximum	4.2	1.0	4.3	0.8	4.4	1.0

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.1

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（1/38）

AST (GOT)

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	137	2	139	-	126	-	126	-	124	-	124
High	-	1	1	2	-	2	4	6	-	2	1	3
Total	-	138	3	141	-	128	4	132	-	126	1	127
Week 6												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	135	1	136	-	119	1	120	-	119	-	119
High	-	1	2	3	-	4	3	7	-	2	1	3
Total	-	136	3	139	-	123	4	127	-	121	1	122
Week 14												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	122	1	123	-	114	1	115	-	110	1	111
High	-	3	2	5	-	2	3	5	-	1	-	1
Total	-	125	3	128	-	116	4	120	-	111	1	112
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	120	2	122	-	103	1	104	-	106	1	107
High	-	-	1	1	-	1	3	4	-	1	-	1
Total	-	120	3	123	-	104	4	108	-	107	1	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（2/38）

AST (GOT)

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	116	2	118	-	101	3	104	-	103	1	104
High	-	1	1	2	-	-	1	1	-	1	-	1
Total	-	117	3	120	-	101	4	105	-	104	1	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（3/38）

ALT (GPT)

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	1	6	-	7	2	-	-	2	1	2	-	3
Normal	5	128	-	133	3	127	-	130	6	112	1	119
High	-	-	1	1	-	1	-	1	-	4	1	5
Total	6	134	1	141	5	128	-	133	7	118	2	127
Week 6												
Low	-	4	-	4	2	2	-	4	2	4	-	6
Normal	6	127	1	134	3	118	-	121	3	110	1	114
High	-	1	-	1	-	2	-	2	-	1	1	2
Total	6	132	1	139	5	122	-	127	5	115	2	122
Week 14												
Low	-	8	-	8	2	6	-	8	1	1	-	2
Normal	5	114	-	119	3	107	-	110	3	105	1	109
High	-	1	1	2	-	3	-	3	-	-	1	1
Total	5	123	1	129	5	116	-	121	4	106	2	112
Week 20												
Low	-	5	-	5	1	2	-	3	1	1	-	2
Normal	5	111	-	116	2	104	-	106	3	100	2	105
High	-	1	1	2	-	1	-	1	-	1	-	1
Total	5	117	1	123	3	107	-	110	4	102	2	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（4/38）

ALT (GPT)

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	6	-	6	1	-	-	1	1	3	-	4
Normal	4	108	-	112	2	103	-	105	3	95	2	100
High	-	1	1	2	-	1	-	1	-	1	-	1
Total	4	115	1	120	3	104	-	107	4	99	2	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（5/38）

GGT

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	126	3	129	-	115	1	116	-	111	2	113
High	-	4	8	12	-	3	14	17	-	4	10	14
Total	-	130	11	141	-	118	15	133	-	115	12	127
Week 6												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	125	2	127	-	109	2	111	-	106	3	109
High	-	3	9	12	-	4	12	16	-	4	9	13
Total	-	128	11	139	-	113	14	127	-	110	12	122
Week 14												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	112	4	116	-	105	4	109	-	95	6	101
High	-	6	7	13	-	3	9	12	-	6	5	11
Total	-	118	11	129	-	108	13	121	-	101	11	112
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	105	4	109	-	96	2	98	-	92	4	96
High	-	7	7	14	-	4	8	12	-	5	7	12
Total	-	112	11	123	-	100	10	110	-	97	11	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（6/38）

GGT

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	104	4	108	-	94	3	97	-	91	6	97
High	-	5	7	12	-	3	7	10	-	4	4	8
Total	-	109	11	120	-	97	10	107	-	95	10	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（7/38）

Alkaline Phosphatase

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	2	-	-	2	-	-	-	-	-	-	-	-
Normal	-	108	6	114	-	94	7	101	-	107	2	109
High	-	4	21	25	-	8	24	32	-	7	11	18
Total	2	112	27	141	-	102	31	133	-	114	13	127
Week 6												
Low	2	1	-	3	-	-	-	-	-	-	-	-
Normal	-	106	6	112	-	92	8	100	-	106	2	108
High	-	3	21	24	-	5	22	27	-	3	11	14
Total	2	110	27	139	-	97	30	127	-	109	13	122
Week 14												
Low	2	-	-	2	-	-	-	-	-	-	-	-
Normal	-	94	9	103	-	89	7	96	-	88	1	89
High	-	7	17	24	-	4	21	25	-	11	12	23
Total	2	101	26	129	-	93	28	121	-	99	13	112
Week 20												
Low	2	-	-	2	-	-	-	-	-	-	-	-
Normal	-	90	10	100	-	78	8	86	-	88	-	88
High	-	7	14	21	-	6	18	24	-	9	11	20
Total	2	97	24	123	-	84	26	110	-	97	11	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（8/38）

Alkaline Phosphatase

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	2	-	-	2	-	-	-	-	-	1	-	1
Normal	-	90	11	101	-	76	8	84	-	89	2	91
High	-	4	13	17	-	6	17	23	-	4	9	13
Total	2	94	24	120	-	82	25	107	-	94	11	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（9/38）

LDH

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	1	-	-	1	-	-	-	-	1	1	-	2
Normal	-	125	3	128	-	112	3	115	-	108	2	110
High	-	3	9	12	-	6	11	17	-	5	10	15
Total	1	128	12	141	-	118	14	132	1	114	12	127
Week 6												
Low	-	-	-	-	-	-	-	-	1	-	-	1
Normal	1	123	7	131	-	105	6	111	-	109	3	112
High	-	3	5	8	-	8	8	16	-	-	9	9
Total	1	126	12	139	-	113	14	127	1	109	12	122
Week 14												
Low	-	-	-	-	-	-	-	-	1	1	-	2
Normal	1	111	4	116	-	102	5	107	-	94	3	97
High	-	4	8	12	-	6	7	13	-	4	9	13
Total	1	115	12	128	-	108	12	120	1	99	12	112
Week 20												
Low	1	-	-	1	-	-	-	-	1	-	-	1
Normal	-	103	3	106	-	97	3	100	-	91	3	94
High	-	8	8	16	-	2	6	8	-	5	8	13
Total	1	111	11	123	-	99	9	108	1	96	11	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（10/38）

LDH

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	1	-	-	1	-	-	-	-	1	-	-	1
Normal	-	100	4	104	-	90	3	93	-	88	4	92
High	-	10	5	15	-	6	6	12	-	6	6	12
Total	1	110	9	120	-	96	9	105	1	94	10	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（11/38）

Albumin

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	1	-	1	1	1	-	2	-	2	-	2
Normal	-	140	-	140	-	131	-	131	1	124	-	125
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	141	-	141	1	132	-	133	1	126	-	127
Week 6												
Low	-	3	-	3	1	1	-	2	-	1	-	1
Normal	-	136	-	136	-	125	-	125	1	120	-	121
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	139	-	139	1	126	-	127	1	121	-	122
Week 14												
Low	-	-	-	-	1	1	-	2	-	-	-	-
Normal	-	129	-	129	-	119	-	119	1	111	-	112
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	129	-	129	1	120	-	121	1	111	-	112
Week 20												
Low	-	1	-	1	-	3	-	3	-	1	-	1
Normal	-	122	-	122	-	107	-	107	1	106	-	107
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	123	-	123	-	110	-	110	1	107	-	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（12/38）

Albumin

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	1	-	1	-	4	-	4	-	-	-	-
Normal	-	119	-	119	-	103	-	103	1	104	-	105
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	120	-	120	-	107	-	107	1	104	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（13/38）

Total Protein

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	19	10	-	29	19	6	-	25	21	14	-	35
Normal	15	97	-	112	9	99	-	108	8	84	-	92
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	34	107	-	141	28	105	-	133	29	98	-	127
Week 6												
Low	22	13	-	35	14	10	-	24	23	10	-	33
Normal	12	92	-	104	11	92	-	103	5	84	-	89
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	34	105	-	139	25	102	-	127	28	94	-	122
Week 14												
Low	22	12	-	34	15	11	-	26	19	12	-	31
Normal	9	86	-	95	8	86	-	94	7	74	-	81
High	-	-	-	-	-	1	-	1	-	-	-	-
Total	31	98	-	129	23	98	-	121	26	86	-	112
Week 20												
Low	22	12	-	34	11	12	-	23	18	17	-	35
Normal	6	83	-	89	9	77	-	86	8	65	-	73
High	-	-	-	-	-	1	-	1	-	-	-	-
Total	28	95	-	123	20	90	-	110	26	82	-	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（14/38）

Total Protein

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	22	13	-	35	12	12	-	24	19	11	-	30
Normal	5	80	-	85	8	75	-	83	7	68	-	75
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	27	93	-	120	20	87	-	107	26	79	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（15/38）

Total Bilirubin

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	127	2	129	-	125	3	128	-	117	4	121
High	-	6	6	12	-	-	5	5	-	1	5	6
Total	-	133	8	141	-	125	8	133	-	118	9	127
Week 6												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	129	3	132	-	119	3	122	-	111	2	113
High	-	2	5	7	-	-	5	5	-	2	7	9
Total	-	131	8	139	-	119	8	127	-	113	9	122
Week 14												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	115	4	119	-	111	4	115	-	105	2	107
High	-	6	4	10	-	2	4	6	-	-	5	5
Total	-	121	8	129	-	113	8	121	-	105	7	112
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	113	3	116	-	100	3	103	-	99	4	103
High	-	3	4	7	-	2	5	7	-	1	4	5
Total	-	116	7	123	-	102	8	110	-	100	8	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（16/38）

Total Bilirubin

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	110	4	114	-	97	2	99	-	95	2	97
High	-	3	3	6	-	2	6	8	-	2	6	8
Total	-	113	7	120	-	99	8	107	-	97	8	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（17/38）

Total Cholesterol

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	106	8	114	2	92	4	98	-	88	4	92
High	-	8	19	27	-	9	26	35	-	11	24	35
Total	-	114	27	141	2	101	30	133	-	99	28	127
Week 6												
Low	-	-	-	-	1	-	-	1	-	1	-	1
Normal	-	105	9	114	1	89	4	94	-	84	5	89
High	-	8	17	25	-	7	25	32	-	10	22	32
Total	-	113	26	139	2	96	29	127	-	95	27	122
Week 14												
Low	-	-	-	-	2	1	-	3	-	-	-	-
Normal	-	103	8	111	-	81	9	90	-	82	5	87
High	-	2	16	18	-	9	19	28	-	5	20	25
Total	-	105	24	129	2	91	28	121	-	87	25	112
Week 20												
Low	-	-	-	-	1	-	-	1	-	-	-	-
Normal	-	95	9	104	1	74	11	86	-	81	8	89
High	-	6	13	19	-	9	14	23	-	5	14	19
Total	-	101	22	123	2	83	25	110	-	86	22	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（18/38）

Total Cholesterol

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	-	-	-	1	1	-	2	-	-	-	-
Normal	-	91	10	101	1	74	11	86	-	75	9	84
High	-	7	12	19	-	6	13	19	-	8	13	21
Total	-	98	22	120	2	81	24	107	-	83	22	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（19/38）

Triglycerides

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	1	-	1	-	-	-	-	-	1	-	1
Normal	-	123	2	125	2	110	9	121	-	105	4	109
High	-	5	10	15	-	8	4	12	-	6	11	17
Total	-	129	12	141	2	118	13	133	-	112	15	127
Week 6												
Low	-	2	-	2	-	1	-	1	-	-	-	-
Normal	-	119	4	123	2	107	5	114	-	98	8	106
High	-	6	8	14	-	5	7	12	-	9	7	16
Total	-	127	12	139	2	113	12	127	-	107	15	122
Week 14												
Low	-	1	-	1	-	-	-	-	-	1	-	1
Normal	-	114	6	120	2	105	8	115	-	92	6	98
High	-	3	5	8	-	2	4	6	-	5	8	13
Total	-	118	11	129	2	107	12	121	-	98	14	112
Week 20												
Low	-	2	-	2	-	-	-	-	-	1	-	1
Normal	-	104	6	110	2	94	6	102	-	91	4	95
High	-	6	5	11	-	3	5	8	-	3	9	12
Total	-	112	11	123	2	97	11	110	-	95	13	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（20/38）

Triglycerides

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	1	-	1	-	-	-	-	-	-	-	-
Normal	-	101	4	105	2	92	5	99	-	87	5	92
High	-	7	7	14	-	2	6	8	-	5	8	13
Total	-	109	11	120	2	94	11	107	-	92	13	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（21/38）

Creatinine

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	8	2	-	10	5	1	-	6	4	2	-	6
Normal	2	120	1	123	3	110	5	118	3	100	4	107
High	-	1	7	8	-	-	9	9	-	3	11	14
Total	10	123	8	141	8	111	14	133	7	105	15	127
Week 6												
Low	8	3	-	11	4	1	-	5	5	1	-	6
Normal	2	117	2	121	3	106	6	115	2	94	4	100
High	-	1	6	7	-	-	7	7	-	6	10	16
Total	10	121	8	139	7	107	13	127	7	101	14	122
Week 14												
Low	5	3	-	8	5	3	-	8	5	1	-	6
Normal	5	108	2	115	2	97	8	107	2	86	2	90
High	-	2	4	6	-	1	5	6	-	4	12	16
Total	10	113	6	129	7	101	13	121	7	91	14	112
Week 20												
Low	5	2	-	7	4	-	-	4	5	1	-	6
Normal	3	101	2	106	2	89	8	99	2	82	4	88
High	-	6	4	10	-	3	4	7	-	4	10	14
Total	8	109	6	123	6	92	12	110	7	87	14	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（22/38）

Creatinine

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	6	3	-	9	4	2	-	6	3	1	-	4
Normal	2	99	1	102	2	85	8	95	4	79	4	87
High	-	4	5	9	-	2	4	6	-	4	10	14
Total	8	106	6	120	6	89	12	107	7	84	14	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（23/38）

Blood Urea Nitrogen

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	118	7	125	-	116	4	120	-	107	10	117
High	-	6	10	16	-	4	9	13	-	8	2	10
Total	-	124	17	141	-	120	13	133	-	115	12	127
Week 6												
Low	-	-	-	-	-	1	-	1	-	-	-	-
Normal	-	117	8	125	-	107	10	117	-	104	6	110
High	-	6	8	14	-	7	2	9	-	7	5	12
Total	-	123	16	139	-	115	12	127	-	111	11	122
Week 14												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	112	10	122	-	98	9	107	-	90	5	95
High	-	2	5	7	-	11	3	14	-	11	6	17
Total	-	114	15	129	-	109	12	121	-	101	11	112
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	99	9	108	-	95	7	102	-	89	7	96
High	-	10	5	15	-	5	3	8	-	8	4	12
Total	-	109	14	123	-	100	10	110	-	97	11	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（24/38）

Blood Urea Nitrogen

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	100	8	108	-	91	6	97	-	85	5	90
High	-	7	5	12	-	6	4	10	-	9	6	15
Total	-	107	13	120	-	97	10	107	-	94	11	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（25/38）

Uric Acid

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	11	4	-	15	5	6	-	11	8	1	-	9
Normal	4	117	-	121	7	108	1	116	2	115	-	117
High	-	1	4	5	-	3	3	6	-	1	-	1
Total	15	122	4	141	12	117	4	133	10	117	-	127
Week 6												
Low	11	1	-	12	8	9	-	17	5	2	-	7
Normal	4	119	1	124	4	102	2	108	4	109	-	113
High	-	-	3	3	-	-	2	2	-	2	-	2
Total	15	120	4	139	12	111	4	127	9	113	-	122
Week 14												
Low	11	1	-	12	9	6	-	15	7	1	-	8
Normal	3	111	1	115	3	97	1	101	2	102	-	104
High	-	-	2	2	-	2	3	5	-	-	-	-
Total	14	112	3	129	12	105	4	121	9	103	-	112
Week 20												
Low	11	1	-	12	7	8	-	15	8	3	-	11
Normal	1	104	2	107	4	86	1	91	1	95	-	96
High	-	3	1	4	-	1	3	4	-	1	-	1
Total	12	108	3	123	11	95	4	110	9	99	-	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（26/38）

Uric Acid

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	10	3	-	13	5	6	-	11	7	2	-	9
Normal	2	99	1	102	5	86	1	92	2	93	-	95
High	-	3	2	5	-	1	3	4	-	1	-	1
Total	12	105	3	120	10	93	4	107	9	96	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（27/38）

CK (CPK)

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	1	-	1	3	1	-	4	1	2	-	3
Normal	1	116	8	125	-	84	10	94	-	90	9	99
High	-	9	6	15	-	16	19	35	-	8	17	25
Total	1	126	14	141	3	101	29	133	1	100	26	127
Week 6												
Low	-	2	-	2	1	1	-	2	1	-	-	1
Normal	1	112	9	122	2	86	10	98	-	92	10	102
High	-	10	5	15	-	10	17	27	-	4	15	19
Total	1	124	14	139	3	97	27	127	1	96	25	122
Week 14												
Low	-	3	-	3	1	1	-	2	1	-	-	1
Normal	1	103	6	110	2	84	11	97	-	81	7	88
High	-	11	5	16	-	9	13	22	-	9	14	23
Total	1	117	11	129	3	94	24	121	1	90	21	112
Week 20												
Low	1	2	-	3	1	1	-	2	1	-	-	1
Normal	-	101	4	105	2	76	12	90	-	79	10	89
High	-	9	6	15	-	9	9	18	-	7	11	18
Total	1	112	10	123	3	86	21	110	1	86	21	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（28/38）

CK (CPK)

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	4	-	4	-	1	-	1	1	-	-	1
Normal	1	90	6	97	3	72	11	86	-	75	11	86
High	-	16	3	19	-	10	10	20	-	9	9	18
Total	1	110	9	120	3	83	21	107	1	84	20	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（29/38）

Sodium

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	4	-	-	4	4	3	-	7	5	3	-	8
Normal	1	136	-	137	1	124	1	126	-	119	-	119
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	5	136	-	141	5	127	1	133	5	122	-	127
Week 6												
Low	1	1	-	2	4	2	-	6	3	4	-	7
Normal	3	134	-	137	1	119	1	121	1	114	-	115
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	135	-	139	5	121	1	127	4	118	-	122
Week 14												
Low	1	1	-	2	5	-	-	5	1	2	-	3
Normal	3	124	-	127	-	116	-	116	3	106	-	109
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	125	-	129	5	116	-	121	4	108	-	112
Week 20												
Low	-	1	-	1	4	-	-	4	2	2	-	4
Normal	4	118	-	122	1	105	-	106	1	103	-	104
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	119	-	123	5	105	-	110	3	105	-	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（30/38）

Sodium

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	-	-	-	4	-	-	4	2	3	-	5
Normal	4	116	-	120	1	102	-	103	1	99	-	100
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	116	-	120	5	102	-	107	3	102	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（31/38）

Potassium

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	1	1	-	2	1	2	-	3	1	1	-	2
Normal	-	138	1	139	1	124	2	127	1	122	-	123
High	-	-	-	-	-	2	-	2	-	2	-	2
Total	1	139	1	141	2	128	2	132	2	125	-	127
Week 6												
Low	1	1	-	2	2	2	-	4	-	2	-	2
Normal	-	136	1	137	1	119	2	122	2	117	-	119
High	-	-	-	-	-	1	-	1	-	1	-	1
Total	1	137	1	139	3	122	2	127	2	120	-	122
Week 14												
Low	1	-	-	1	1	-	-	1	-	-	-	-
Normal	-	124	1	125	1	115	2	118	2	108	-	110
High	-	2	-	2	-	1	-	1	-	2	-	2
Total	1	126	1	128	2	116	2	120	2	110	-	112
Week 20												
Low	1	-	-	1	-	1	-	1	1	3	-	4
Normal	-	118	1	119	2	103	1	106	1	101	-	102
High	-	3	-	3	-	1	-	1	-	2	-	2
Total	1	121	1	123	2	105	1	108	2	106	-	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（32/38）

Potassium

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	1	-	1	-	-	-	-	-	-	-	-
Normal	1	115	1	117	2	102	1	105	1	102	-	103
High	-	2	-	2	-	-	-	-	-	2	-	2
Total	1	118	1	120	2	102	1	105	1	104	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（33/38）

Chloride

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	-	-	-	2	3	-	5	2	-	-	2
Normal	2	136	1	139	1	122	4	127	-	119	3	122
High	-	1	1	2	-	1	-	1	-	2	1	3
Total	2	137	2	141	3	126	4	133	2	121	4	127
Week 6												
Low	1	-	-	1	2	2	-	4	-	-	-	-
Normal	1	133	1	135	1	114	3	118	1	116	3	120
High	-	2	1	3	-	4	1	5	-	1	1	2
Total	2	135	2	139	3	120	4	127	1	117	4	122
Week 14												
Low	2	1	-	3	1	1	-	2	1	-	-	1
Normal	-	120	1	121	2	113	3	118	-	107	3	110
High	-	5	-	5	-	-	1	1	-	1	-	1
Total	2	126	1	129	3	114	4	121	1	108	3	112
Week 20												
Low	-	-	-	-	1	1	-	2	1	-	-	1
Normal	2	113	1	116	2	101	4	107	-	103	3	106
High	-	7	-	7	-	1	-	1	-	1	-	1
Total	2	120	1	123	3	103	4	110	1	104	3	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（34/38）

Chloride

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	-	-	-	2	-	-	2	1	3	-	4
Normal	2	114	1	117	1	98	3	102	-	96	3	99
High	-	3	-	3	-	2	1	3	-	2	-	2
Total	2	117	1	120	3	100	4	107	1	101	3	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（35/38）

Calcium

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	2	2	-	4	-	1	-	1	-	1	-	1
Normal	1	136	-	137	-	132	-	132	1	125	-	126
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	3	138	-	141	-	133	-	133	1	126	-	127
Week 6												
Low	2	1	-	3	-	-	-	-	1	2	-	3
Normal	1	135	-	136	-	127	-	127	-	119	-	119
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	3	136	-	139	-	127	-	127	1	121	-	122
Week 14												
Low	-	5	-	5	-	2	-	2	1	-	-	1
Normal	3	121	-	124	-	119	-	119	-	111	-	111
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	3	126	-	129	-	121	-	121	1	111	-	112
Week 20												
Low	1	1	-	2	-	1	-	1	1	2	-	3
Normal	2	119	-	121	-	109	-	109	-	105	-	105
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	3	120	-	123	-	110	-	110	1	107	-	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（36/38）

Calcium

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	-	2	-	2	-	3	-	3	1	1	-	2
Normal	3	115	-	118	-	104	-	104	-	103	-	103
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	3	117	-	120	-	107	-	107	1	104	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（37/38）

Phosphorus

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 3												
Low	-	3	-	3	2	3	-	5	1	3	-	4
Normal	5	132	-	137	1	126	-	127	2	121	-	123
High	-	1	-	1	-	1	-	1	-	-	-	-
Total	5	136	-	141	3	130	-	133	3	124	-	127
Week 6												
Low	1	3	-	4	1	-	-	1	-	2	-	2
Normal	4	131	-	135	2	124	-	126	3	117	-	120
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	5	134	-	139	3	124	-	127	3	119	-	122
Week 14												
Low	1	3	-	4	2	2	-	4	-	1	-	1
Normal	4	121	-	125	-	117	-	117	2	107	-	109
High	-	-	-	-	-	-	-	-	-	2	-	2
Total	5	124	-	129	2	119	-	121	2	110	-	112
Week 20												
Low	-	3	-	3	-	2	-	2	-	1	-	1
Normal	5	114	-	119	1	107	-	108	2	105	-	107
High	-	1	-	1	-	-	-	-	-	-	-	-
Total	5	118	-	123	1	109	-	110	2	106	-	108

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-68　血液生化学検査の正異判定のクロス表（CCT-002 試験）（38/38）

Phosphorus

	Baseline											
	Placebo (N=141)				0.5 mg (N=133)				1 mg (N=129)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 26												
Low	1	-	-	1	1	-	-	1	-	1	-	1
Normal	4	115	-	119	-	106	-	106	2	102	-	104
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	5	115	-	120	1	106	-	107	2	103	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.1.3

表 2.7.4.7-付録-69　尿検査の正異判定のクロス表（CCT-002 試験）（1/8）

Protein

	Baseline																					
	Placebo (N=141)							0.5 mg (N=133)							1 mg (N=129)							
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 3																					
-	124	6	1	-	-	-	131	106	8	1	-	-	-	115	111	2	1	-	-	-	114
+-	3	3	1	-	-	-	7	8	5	-	-	-	-	13	6	-	1	-	-	-	7
1+	-	-	-	-	-	-	-	3	1	-	-	-	-	4	5	1	-	-	-	-	6
2+	-	-	-	2	-	-	2	-	-	1	-	-	-	1	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	127	9	2	2	-	-	140	117	14	2	-	-	-	133	122	3	2	-	-	-	127
Week 6																					
-	120	7	2	-	-	-	129	104	8	-	-	-	-	112	108	2	1	-	-	-	111
+-	6	1	-	-	-	-	7	6	3	1	-	-	-	10	5	-	-	-	-	-	5
1+	-	1	-	-	-	-	1	3	1	1	-	-	-	5	5	-	-	-	-	-	5
2+	-	-	-	2	-	-	2	-	-	-	-	-	-	-	1	-	-	-	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	126	9	2	2	-	-	139	113	12	2	-	-	-	127	119	2	1	-	-	-	122
Week 14																					
-	114	4	1	-	-	-	119	103	6	-	-	-	-	109	93	2	-	-	-	-	95
+-	3	2	1	-	-	-	6	3	5	2	-	-	-	10	8	-	1	-	-	-	9
1+	1	1	-	-	-	-	2	1	-	-	-	-	-	1	7	-	-	-	-	-	7
2+	-	-	-	2	-	-	2	1	-	-	-	-	-	1	1	-	-	-	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	118	7	2	2	-	-	129	108	11	2	-	-	-	121	109	2	1	-	-	-	112

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.2

表 2.7.4.7-付録-69　尿検査の正異判定のクロス表（CCT-002 試験）（2/8）

Protein

	Baseline																				
	Placebo (N=141)							0.5 mg (N=133)							1 mg (N=129)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 20																					
-	107	4	1	-	-	-	112	91	6	-	-	-	-	97	93	2	1	-	-	-	96
+-	4	1	-	-	-	-	5	5	3	2	-	-	-	10	8	-	-	-	-	-	8
1+	-	1	1	-	-	-	2	2	1	-	-	-	-	3	4	-	-	-	-	-	4
2+	1	1	-	2	-	-	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	112	7	2	2	-	-	123	98	10	2	-	-	-	110	105	2	1	-	-	-	108
Week 26																					
-	104	5	1	-	-	-	110	90	7	-	-	-	-	97	88	2	1	-	-	-	91
+-	5	1	1	-	-	-	7	4	-	2	-	-	-	6	6	-	-	-	-	-	6
1+	-	-	-	-	-	-	-	2	2	-	-	-	-	4	6	-	-	-	-	-	6
2+	-	1	-	2	-	-	3	-	-	-	-	-	-	-	2	-	-	-	-	-	2
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	109	7	2	2	-	-	120	96	9	2	-	-	-	107	102	2	1	-	-	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.2

表 2.7.4.7-付録-69　尿検査の正異判定のクロス表（CCT-002 試験）（3/8）

Glucose

	Baseline																				
	Placebo (N=141)							0.5 mg (N=133)							1 mg (N=129)						
Visit	-	1+	2+	3+	4+	5+	Total	-	1+	2+	3+	4+	5+	Total	-	1+	2+	3+	4+	5+	Total
Week 3																					
-	133	2	1	-	-	1	137	130	-	-	-	-	-	130	122	1	-	-	1	-	124
1+	1	-	-	-	-	-	1	-	1	-	-	-	-	1	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	1	-	-	-	-	-	1	-	-	-	1	-	-	1
3+	-	-	-	-	1	-	1	-	-	-	1	-	-	1	-	-	1	-	-	-	1
4+	-	-	-	1	-	-	1	-	-	-	-	-	-	-	-	-	-	-	1	-	1
5+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	134	2	1	1	1	1	140	131	1	-	1	-	-	133	122	1	1	1	2	-	127
Week 6																					
-	133	2	1	-	-	1	137	125	-	-	-	-	-	125	113	1	-	-	1	-	115
1+	-	-	-	-	-	-	-	-	1	-	-	-	-	1	1	-	1	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	1
3+	-	-	-	1	1	-	2	-	-	-	-	-	-	-	2	-	-	1	-	-	3
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5+	-	-	-	-	-	-	-	-	-	-	1	-	-	1	-	-	-	-	1	-	1
Total	133	2	1	1	1	1	139	125	1	-	1	-	-	127	117	1	1	1	2	-	122
Week 14																					
-	121	1	1	-	-	1	124	118	-	-	-	-	-	118	107	1	-	-	1	-	109
1+	1	-	-	-	1	-	2	1	1	-	-	-	-	2	1	-	-	-	-	-	1
2+	2	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	1	-	-	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	1	-	-	1	-	-	-	-	-	-	-	-	-	-	1	-	-	1
5+	-	-	-	-	-	-	-	-	-	-	1	-	-	1	-	-	-	-	-	-	-
Total	124	1	1	1	1	1	129	119	1	-	1	-	-	121	108	1	1	1	1	-	112

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.2

表 2.7.4.7-付録-69　尿検査の正異判定のクロス表（CCT-002 試験）（4/8）

Glucose

	Baseline																				
	Placebo (N=141)							0.5 mg (N=133)							1 mg (N=129)						
Visit	-	1+	2+	3+	4+	5+	Total	-	1+	2+	3+	4+	5+	Total	-	1+	2+	3+	4+	5+	Total
Week 20																					
-	118	-	1	-	1	1	121	107	1	-	-	-	-	108	100	-	-	-	1	-	101
1+	-	-	-	-	-	-	-	1	-	-	-	-	-	1	1	1	-	-	-	-	2
2+	1	-	-	-	-	-	1	1	-	-	-	-	-	1	2	-	-	-	-	-	2
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	1
4+	-	-	-	1	-	-	1	-	-	-	-	-	-	-	-	-	-	1	1	-	2
5+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	119	-	1	1	1	1	123	109	1	-	-	-	-	110	103	1	1	1	2	-	108
Week 26																					
-	114	-	1	-	-	1	116	107	-	-	-	-	-	107	99	-	-	-	-	-	99
1+	1	-	-	1	-	-	2	-	-	-	-	-	-	-	1	1	-	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	1	-	-	-	1	-	2	-	-	-	-	-	-	-	-	-	1	1	-	-	2
5+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	116	-	1	1	1	1	120	107	-	-	-	-	-	107	100	1	1	1	2	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.2

表 2.7.4.7-付録-69　尿検査の正異判定のクロス表（CCT-002 試験）（5/8）

Occult Blood

	Baseline																	
	Placebo (N=141)						0.5 mg (N=133)						1 mg (N=129)					
Visit	-	+-	1+	2+	3+	Total	-	+-	1+	2+	3+	Total	-	+-	1+	2+	3+	Total
Week 3																		
-	127	-	1	1	-	129	121	2	-	-	-	123	109	1	2	1	1	114
+-	2	-	-	-	-	2	1	-	-	-	-	1	3	-	-	-	-	3
1+	1	1	-	1	-	3	4	-	2	-	-	6	2	1	-	1	-	4
2+	2	-	-	1	-	3	1	-	-	-	-	1	1	-	-	2	-	3
3+	2	1	-	-	-	3	1	-	-	-	1	2	2	-	-	1	-	3
Total	134	2	1	3	-	140	128	2	2	-	1	133	117	2	2	5	1	127
Week 6																		
-	128	-	1	1	-	130	119	-	-	-	-	119	108	2	1	2	1	114
+-	-	-	-	-	-	-	1	1	1	-	-	3	-	-	-	-	-	-
1+	1	1	-	-	-	2	1	-	-	-	-	1	1	-	-	1	-	2
2+	3	1	-	2	-	6	1	1	-	-	-	2	2	-	-	1	-	3
3+	1	-	-	-	-	1	-	-	1	-	1	2	1	-	1	1	-	3
Total	133	2	1	3	-	139	122	2	2	-	1	127	112	2	2	5	1	122
Week 14																		
-	123	1	-	-	-	124	110	2	1	-	-	113	99	2	1	-	1	103
+-	-	-	-	1	-	1	1	-	-	-	-	1	1	-	-	-	-	1
1+	-	1	1	-	-	2	3	-	1	-	-	4	2	-	1	-	-	3
2+	-	-	-	2	-	2	2	-	-	-	-	2	1	-	-	4	-	5
3+	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-
Total	123	2	1	3	-	129	116	2	2	-	1	121	103	2	2	4	1	112

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.2

表 2.7.4.7-付録-69　尿検査の正異判定のクロス表（CCT-002 試験）（6/8）

Occult Blood

	Baseline																	
	Placebo (N=141)						0.5 mg (N=133)						1 mg (N=129)					
Visit	-	+-	1+	2+	3+	Total	-	+-	1+	2+	3+	Total	-	+-	1+	2+	3+	Total
Week 20																		
-	111	-	-	-	-	111	99	1	2	-	-	102	98	-	1	-	1	100
+-	2	-	-	-	-	2	1	-	-	-	-	1	1	-	-	1	-	2
1+	2	1	1	1	-	5	3	1	-	-	-	4	-	2	-	-	-	2
2+	1	-	-	2	-	3	1	-	-	-	1	2	-	-	1	3	-	4
3+	2	-	-	-	-	2	1	-	-	-	-	1	-	-	-	-	-	-
Total	118	1	1	3	-	123	105	2	2	-	1	110	99	2	2	4	1	108
Week 26																		
-	108	-	-	1	-	109	96	2	2	-	-	100	95	2	2	-	1	100
+-	1	-	-	-	-	1	1	-	-	-	-	1	-	-	-	-	-	-
1+	6	1	-	-	-	7	3	-	-	-	-	3	1	-	-	2	-	3
2+	-	-	1	1	-	2	1	-	-	-	1	2	-	-	-	1	-	1
3+	-	-	-	1	-	1	1	-	-	-	-	1	-	-	-	1	-	1
Total	115	1	1	3	-	120	102	2	2	-	1	107	96	2	2	4	1	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.2

表 2.7.4.7-付録-69　尿検査の正異判定のクロス表（CCT-002 試験）（7/8）

Ketones

	Baseline																					
	Placebo (N=141)							0.5 mg (N=133)							1 mg (N=129)							
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 3																					
-	90	17	1	-	-	-	108	89	11	3	-	-	-	103	86	14	-	-	-	-	100
+-	10	15	4	-	-	-	29	14	11	2	-	-	-	27	9	17	-	-	-	-	26
1+	-	2	-	-	-	-	2	1	1	-	1	-	-	3	-	1	-	-	-	-	1
2+	-	1	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	100	35	5	-	-	-	140	104	23	5	1	-	-	133	95	32	-	-	-	-	127
Week 6																					
-	86	20	1	-	-	-	107	87	10	1	-	-	-	98	80	14	-	-	-	-	94
+-	13	14	4	-	-	-	31	12	10	2	-	-	-	24	12	15	-	-	-	-	27
1+	-	1	-	-	-	-	1	3	-	1	-	-	-	4	1	-	-	-	-	-	1
2+	-	-	-	-	-	-	-	-	-	-	1	-	-	1	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	99	35	5	-	-	-	139	102	20	4	1	-	-	127	93	29	-	-	-	-	122
Week 14																					
-	82	11	-	-	-	-	93	84	8	2	-	-	-	94	76	15	-	-	-	-	91
+-	9	19	4	-	-	-	32	13	9	2	1	-	-	25	10	10	-	-	-	-	20
1+	2	1	-	-	-	-	3	1	1	-	-	-	-	2	-	1	-	-	-	-	1
2+	-	1	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	93	32	4	-	-	-	129	98	18	4	1	-	-	121	86	26	-	-	-	-	112

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.2

表 2.7.4.7-付録-69　尿検査の正異判定のクロス表（CCT-002 試験）（8/8）

Ketones

	Baseline																			
	Placebo (N=141)							0.5 mg (N=133)							1 mg (N=129)						
Visit	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total	-	+-	1+	2+	3+	4+	Total
Week 20																					
-	70	18	3	-	-	-	91	76	4	2	-	-	-	82	67	13	-	-	-	-	80
+-	16	10	1	-	-	-	27	15	10	-	1	-	-	26	16	10	-	-	-	-	26
1+	2	3	-	-	-	-	5	-	1	1	-	-	-	2	1	1	-	-	-	-	2
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	88	31	4	-	-	-	123	91	15	3	1	-	-	110	84	24	-	-	-	-	108
Week 26																					
-	71	14	2	-	-	-	87	74	5	1	-	-	-	80	66	12	-	-	-	-	78
+-	13	14	1	-	-	-	28	15	8	1	1	-	-	25	15	12	-	-	-	-	27
1+	2	2	1	-	-	-	5	-	1	1	-	-	-	2	-	-	-	-	-	-	-
2+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	86	30	4	-	-	-	120	89	14	3	1	-	-	107	81	24	-	-	-	-	105

Statistical Analysis Report (5.3.5.1-3) Table 3.3.1.2

表 2.7.4.7-付録-70　血液学的検査の変化量（133 試験）（1/4）

TVP-1012/133 (PRESTO)		0.5 mg			1 mg			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
WBC (x10^3/cumm)	N	163	163	163	145	145	145	158	158	158
	Mean	6.14	5.96	-0.17	6.35	6.52	0.17	6.15	6.18	0.03
	Std	1.47	1.45	1.14	1.60	1.75	1.28	1.51	1.97	1.83
	Median	5.80	5.70	-0.20	6.00	6.20	0.10	5.95	5.90	-0.10
	Min	2.90	2.90	-3.30	3.20	3.30	-3.20	3.40	3.40	-4.00
	Max	11.40	11.60	3.60	12.90	12.50	6.20	13.10	22.80	16.20
Neutrophils (%)	N	163	163	163	145	145	145	158	158	158
	Mean	66.97	66.69	-0.28	66.54	67.30	0.76	66.58	67.63	1.05
	Std	7.40	7.03	6.39	7.52	7.75	6.26	7.96	7.12	6.13
	Median	67.00	66.50	-0.50	65.90	67.30	0.30	66.75	68.60	1.35
	Min	46.80	46.20	-17.20	47.60	48.60	-17.90	38.90	48.40	-22.30
	Max	84.40	81.80	26.90	87.70	87.20	21.70	91.60	87.30	22.10
Lympho-cytes (%)	N	163	163	163	145	145	145	158	158	158
	Mean	24.39	24.45	0.05	24.76	24.19	-0.57	24.34	23.40	-0.94
	Std	6.65	6.15	5.29	6.56	6.77	5.35	7.14	6.72	5.34
	Median	23.40	24.30	0.20	24.90	23.80	-0.10	24.15	22.70	-1.15
	Min	4.20	11.60	-24.10	7.60	8.10	-16.80	2.90	6.00	-17.10
	Max	42.60	45.20	13.10	39.50	43.50	15.40	51.50	42.60	17.00
Monocytes (%)	N	163	163	163	145	145	145	158	158	158
	Mean	6.05	6.27	0.22	6.10	5.96	-0.14	6.62	6.51	-0.11
	Std	1.86	2.05	2.05	1.80	1.75	1.76	1.96	2.27	2.04
	Median	5.80	6.10	0.20	6.10	6.00	-0.20	6.55	6.60	-0.10
	Min	0.10	0.10	-7.60	1.90	0.70	-6.20	3.10	0.00	-7.50
	Max	11.30	15.00	8.60	12.20	10.80	4.10	13.20	14.50	6.30
Eosinophils (%)	N	163	163	163	145	145	145	158	158	158
	Mean	2.20	2.22	0.01	2.24	2.18	-0.06	2.08	2.10	0.02
	Std	1.56	1.38	1.37	1.61	1.63	1.08	1.35	1.47	1.19
	Median	1.90	2.00	0.10	1.90	1.70	-0.10	1.85	1.90	-0.05
	Min	0.10	0.20	-5.60	0.00	0.10	-4.50	0.10	0.10	-2.60
	Max	8.30	7.50	3.50	11.60	9.10	3.00	6.10	9.00	6.60

LOV = Last Observed Value
総括報告書（5.3.5.1-4）Post-Text Table 58

表 2.7.4.7-付録-70　血液学的検査の変化量（133 試験）（2/4）

TVP-1012/133 (PRESTO)		0.5 mg			1 mg			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
Basophils (%)	N	163	163	163	145	145	145	158	158	158
	Mean	0.38	0.37	-0.01	0.36	0.37	0.01	0.37	0.36	-0.01
	Std	0.20	0.18	0.25	0.19	0.26	0.28	0.19	0.24	0.26
	Median	0.30	0.40	0.00	0.30	0.30	0.00	0.35	0.30	0.00
	Min	0.00	0.00	-0.70	0.00	0.00	-0.90	0.00	0.00	-0.70
	Max	0.90	1.40	1.30	1.10	2.10	1.70	1.00	1.80	1.40
Neutrophils absolute (x10^3/uL)	N	163	163	163	145	145	145	158	158	158
	Mean	4.12	4.00	-0.12	4.26	4.43	0.17	4.15	4.22	0.07
	Std	1.14	1.20	1.03	1.34	1.50	1.20	1.39	1.63	1.56
	Median	3.94	3.81	-0.16	3.93	4.17	0.01	3.94	3.98	-0.06
	Min	1.74	1.74	-3.04	1.70	1.88	-3.36	1.88	2.02	-3.97
	Max	8.62	9.30	4.55	10.03	10.82	6.04	10.27	17.78	13.19
Lympho-cytes absolute (x10^3/uL)	N	163	163	163	145	145	145	158	158	158
	Mean	1.49	1.44	-0.05	1.55	1.54	-0.00	1.45	1.42	-0.04
	Std	0.53	0.44	0.35	0.51	0.52	0.32	0.44	0.49	0.37
	Median	1.42	1.40	0.00	1.49	1.50	0.02	1.39	1.36	-0.06
	Min	0.21	0.63	-1.35	0.57	0.52	-1.09	0.32	0.43	-0.97
	Max	4.30	2.96	0.78	3.45	3.92	0.98	2.77	4.10	2.61
Monocytes absolute (x10^3/uL)	N	163	163	163	145	145	145	158	158	158
	Mean	0.37	0.37	-0.00	0.38	0.38	0.00	0.40	0.40	-0.00
	Std	0.14	0.14	0.12	0.14	0.14	0.13	0.13	0.16	0.14
	Median	0.34	0.35	-0.01	0.36	0.38	-0.00	0.38	0.37	-0.00
	Min	0.01	0.01	-0.35	0.09	0.07	-0.55	0.18	0.00	-0.35
	Max	0.97	1.32	0.40	0.84	0.78	0.42	0.85	1.22	0.54
Eosinophils absolute (x10^3/uL)	N	163	163	163	145	145	145	158	158	158
	Mean	0.14	0.13	-0.00	0.14	0.14	-0.00	0.12	0.13	0.00
	Std	0.10	0.08	0.09	0.10	0.10	0.07	0.08	0.10	0.08
	Median	0.11	0.12	0.00	0.12	0.11	0.00	0.11	0.11	-0.00
	Min	0.01	0.01	-0.48	0.00	0.01	-0.24	0.01	0.01	-0.14
	Max	0.75	0.43	0.19	0.65	0.61	0.20	0.40	0.76	0.58

LOV = Last Observed Value

総括報告書（5.3.5.1-4）Post-Text Table 58

表 2.7.4.7-付録-70　血液学的検査の変化量（133 試験）（3/4）

TVP-1012/133 (PRESTO)		0.5 mg			1 mg			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
Basophils absolute (x10^3/uL)	N	163	163	163	145	145	145	158	158	158
	Mean	0.02	0.02	-0.00	0.02	0.02	0.00	0.02	0.02	-0.00
	Std	0.01	0.01	0.02	0.01	0.02	0.02	0.01	0.02	0.02
	Median	0.02	0.02	-0.00	0.02	0.02	-0.00	0.02	0.02	0.00
	Min	0.00	0.00	-0.05	0.00	0.00	-0.04	0.00	0.00	-0.05
	Max	0.08	0.08	0.08	0.07	0.13	0.11	0.06	0.12	0.09
RBC (x10^6/cumm)	N	163	163	163	145	145	145	158	158	158
	Mean	4.47	4.44	-0.03	4.52	4.46	-0.05	4.51	4.53	0.01
	Std	0.42	0.46	0.23	0.44	0.48	0.23	0.46	0.48	0.24
	Median	4.47	4.43	0.00	4.50	4.45	-0.05	4.50	4.53	0.00
	Min	3.28	3.27	-0.72	3.54	3.23	-0.69	3.20	2.83	-0.86
	Max	5.90	5.95	0.50	5.61	5.73	0.57	6.32	6.22	0.79
Hgb (gm/dL)	N	163	163	163	145	145	145	158	158	158
	Mean	13.97	13.81	-0.16	14.07	13.88	-0.18	13.88	13.94	0.06
	Std	1.24	1.34	0.73	1.32	1.39	0.66	1.31	1.29	0.76
	Median	13.90	13.80	-0.10	14.00	14.00	-0.20	13.90	14.00	0.10
	Min	11.50	10.20	-2.80	10.60	9.90	-2.30	10.90	10.30	-2.70
	Max	17.60	17.40	2.10	17.60	17.50	1.50	17.30	16.30	3.40
Hct (%)	N	163	163	163	145	145	145	158	158	158
	Mean	41.51	41.23	-0.27	41.83	41.33	-0.50	41.31	41.78	0.47
	Std	3.59	4.01	2.28	3.99	4.12	2.29	3.69	3.76	2.43
	Median	41.90	41.60	-0.20	41.80	41.50	-0.40	41.10	41.70	0.40
	Min	33.00	29.70	-7.50	33.40	30.50	-7.10	32.80	30.90	-7.60
	Max	53.50	50.70	5.10	52.40	52.20	5.60	50.40	49.60	10.20
MCV (fL)	N	163	163	163	145	145	145	158	158	158
	Mean	92.93	92.90	-0.03	92.73	92.70	-0.03	91.71	92.52	0.80
	Std	4.33	4.31	2.72	4.76	4.51	3.01	5.28	5.27	3.24
	Median	92.90	92.90	-0.10	93.10	92.80	-0.10	91.90	92.20	0.60
	Min	70.30	72.40	-8.20	79.70	77.90	-10.30	66.50	65.00	-7.20
	Max	103.70	104.20	7.40	106.30	104.30	7.70	106.70	109.30	13.10

LOV = Last Observed Value

総括報告書（5.3.5.1-4）Post-Text Table 58

表 2.7.4.7-付録-70　血液学的検査の変化量（133 試験）（4/4）

TVP-1012/133 (PRESTO)		0.5 mg			1 mg			Placebo		
		Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline	Baseline	LOV Result	Change from Baseline
MCH (pg)	N	163	163	163	145	145	145	158	158	158
	Mean	31.29	31.13	-0.16	31.21	31.18	-0.03	30.84	30.90	0.05
	Std	1.47	1.47	0.67	1.62	1.57	0.64	2.03	1.94	0.94
	Median	31.30	31.00	-0.10	31.40	31.40	-0.10	31.00	30.85	0.00
	Min	23.20	22.90	-3.10	25.30	26.40	-1.60	20.50	20.30	-3.80
	Max	35.50	34.90	3.20	35.00	34.70	3.20	35.10	36.50	4.20
MCHC (%)	N	163	163	163	145	145	145	158	158	158
	Mean	33.65	33.50	-0.15	33.64	33.61	-0.03	33.60	33.37	-0.23
	Std	0.69	0.86	1.00	0.90	0.88	1.11	0.92	0.88	1.05
	Median	33.70	33.50	-0.20	33.70	33.60	0.00	33.60	33.45	-0.20
	Min	31.70	30.90	-2.70	31.20	31.40	-2.70	30.10	30.80	-2.60
	Max	35.10	35.40	2.60	36.00	35.70	3.30	35.30	35.60	3.00
Platelet count (x10^3/cumm)	N	162	163	162	144	144	144	157	157	157
	Mean	242.65	242.68	0.54	237.21	244.84	7.63	242.52	237.02	-5.50
	Std	57.33	56.82	29.74	54.47	58.06	36.35	70.58	64.75	39.35
	Median	236.50	238.00	1.00	234.00	239.50	5.00	231.00	224.00	-5.00
	Min	123.00	102.00	-86.00	98.00	119.00	-96.00	119.00	110.00	-260.0
	Max	448.00	397.00	101.00	397.00	584.00	187.00	580.00	434.00	90.00

LOV = Last Observed Value

総括報告書（5.3.5.1-4）Post-Text Table 58