表 2.7.4.7-付録-29　尿検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（1/5）

Laboratory Test: Specific Gravity

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week -12						
N	71		152		151	
Mean	1.0184		1.0165		1.0167	
SD	0.00558		0.00670		0.00691	
Minimum	1.004		1.002		1.002	
Q1	1.0150		1.0110		1.0110	
Median	1.0190		1.0165		1.0180	
Q3	1.0220		1.0210		1.0220	
Maximum	1.030		1.030		1.030	
Week -4						
N	71		152		151	
Mean	1.0193		1.0164		1.0170	
SD	0.00614		0.00671		0.00697	
Minimum	1.002		1.002		1.002	
Q1	1.0150		1.0120		1.0120	
Median	1.0200		1.0160		1.0180	
Q3	1.0240		1.0210		1.0230	
Maximum	1.031		1.031		1.031	

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.1

表 2.7.4.7-付録-29　尿検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（2/5）

Laboratory Test: Specific Gravity

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week 0						
N	71		152		151	
Mean	1.0190		1.0170		1.0170	
SD	0.00597		0.00634		0.00740	
Minimum	1.004		1.002		1.003	
Q1	1.0150		1.0120		1.0110	
Median	1.0190		1.0180		1.0170	
Q3	1.0230		1.0210		1.0220	
Maximum	1.034		1.033		1.031	
Week 2						
N	71	71	152	152	151	151
Mean	1.0189	-0.0002	1.0155	-0.0014	1.0167	-0.0003
SD	0.00586	0.00442	0.00681	0.00640	0.00681	0.00563
Minimum	1.005	-0.010	1.001	-0.024	1.003	-0.019
Q1	1.0150	-0.0040	1.0100	-0.0050	1.0120	-0.0030
Median	1.0190	0.0000	1.0160	-0.0010	1.0170	0.0000
Q3	1.0220	0.0040	1.0200	0.0020	1.0210	0.0030
Maximum	1.031	0.009	1.030	0.014	1.034	0.014

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.1

表 2.7.4.7-付録-29　尿検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（3/5）

Laboratory Test: Specific Gravity

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week 4						
N	70	70	150	150	150	150
Mean	1.0188	-0.0002	1.0160	-0.0010	1.0162	-0.0008
SD	0.00627	0.00630	0.00641	0.00590	0.00676	0.00603
Minimum	1.004	-0.017	1.002	-0.023	1.003	-0.026
Q1	1.0150	-0.0040	1.0110	-0.0040	1.0110	-0.0040
Median	1.0200	0.0000	1.0160	-0.0010	1.0160	0.0000
Q3	1.0240	0.0050	1.0210	0.0030	1.0220	0.0030
Maximum	1.031	0.013	1.034	0.016	1.030	0.018
Week 8						
N	68	68	149	149	149	149
Mean	1.0181	-0.0008	1.0158	-0.0011	1.0167	-0.0003
SD	0.00673	0.00636	0.00666	0.00655	0.00670	0.00566
Minimum	1.002	-0.013	1.002	-0.022	1.002	-0.019
Q1	1.0140	-0.0050	1.0100	-0.0050	1.0120	-0.0040
Median	1.0200	-0.0015	1.0160	-0.0010	1.0170	0.0000
Q3	1.0230	0.0020	1.0210	0.0020	1.0210	0.0030
Maximum	1.031	0.020	1.031	0.017	1.032	0.015

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.1

表 2.7.4.7-付録-29　尿検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（4/5）

Laboratory Test: Specific Gravity

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week 12						
N	67	67	148	148	148	148
Mean	1.0181	-0.0009	1.0156	-0.0013	1.0165	-0.0005
SD	0.00636	0.00646	0.00665	0.00650	0.00698	0.00669
Minimum	1.004	-0.017	1.002	-0.021	1.002	-0.020
Q1	1.0130	-0.0060	1.0110	-0.0050	1.0115	-0.0050
Median	1.0190	0.0000	1.0160	-0.0020	1.0170	-0.0010
Q3	1.0230	0.0030	1.0205	0.0010	1.0210	0.0030
Maximum	1.030	0.020	1.030	0.018	1.030	0.022
Week 16						
N	66	66	148	148	148	148
Mean	1.0178	-0.0011	1.0154	-0.0015	1.0156	-0.0014
SD	0.00558	0.00660	0.00604	0.00631	0.00632	0.00638
Minimum	1.004	-0.016	1.003	-0.022	1.003	-0.023
Q1	1.0140	-0.0060	1.0110	-0.0050	1.0110	-0.0050
Median	1.0180	-0.0020	1.0155	-0.0010	1.0160	-0.0010
Q3	1.0210	0.0030	1.0200	0.0030	1.0200	0.0020
Maximum	1.030	0.020	1.029	0.017	1.031	0.018

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.1

表 2.7.4.7-付録-29　尿検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（5/5）

Laboratory Test: Specific Gravity

Visit / Statistics	Placebo (N=71) Observed Value at Visit	Placebo (N=71) Change from Baseline	QD (N=152) Observed Value at Visit	QD (N=152) Change from Baseline	BID (N=151) Observed Value at Visit	BID (N=151) Change from Baseline
Week 20						
N	65	65	146	146	148	148
Mean	1.0181	-0.0009	1.0146	-0.0023	1.0159	-0.0011
SD	0.00616	0.00717	0.00593	0.00673	0.00639	0.00624
Minimum	1.004	-0.018	1.002	-0.028	1.003	-0.018
Q1	1.0140	-0.0060	1.0100	-0.0050	1.0105	-0.0045
Median	1.0180	-0.0010	1.0150	-0.0020	1.0160	-0.0010
Q3	1.0210	0.0040	1.0190	0.0020	1.0205	0.0020
Maximum	1.030	0.015	1.030	0.015	1.029	0.022
Week 24						
N	64	64	146	146	148	148
Mean	1.0164	-0.0025	1.0152	-0.0018	1.0159	-0.0011
SD	0.00662	0.00637	0.00599	0.00561	0.00679	0.00687
Minimum	1.002	-0.021	1.001	-0.019	1.003	-0.024
Q1	1.0120	-0.0050	1.0110	-0.0050	1.0110	-0.0050
Median	1.0155	-0.0020	1.0150	-0.0015	1.0160	-0.0010
Q3	1.0215	0.0015	1.0190	0.0010	1.0200	0.0020
Maximum	1.034	0.016	1.030	0.012	1.030	0.018

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.1

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（1/12）

Specific Gravity

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	1	-	1	-	-	-	-
Normal	-	67	3	70	-	150	1	151	-	149	1	150
High	-	1	-	1	-	-	-	-	-	1	-	1
Total	-	68	3	71	-	151	1	152	-	150	1	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	66	3	69	-	148	1	149	-	149	1	150
High	-	1	-	1	-	1	-	1	-	-	-	-
Total	-	67	3	70	-	149	1	150	-	149	1	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	65	2	67	-	147	1	148	-	147	1	148
High	-	-	1	1	-	1	-	1	-	1	-	1
Total	-	65	3	68	-	148	1	149	-	148	1	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	64	3	67	-	147	1	148	-	147	1	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	64	3	67	-	147	1	148	-	147	1	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（2/12）

Specific Gravity

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	63	3	66	-	147	1	148	-	146	1	147
High	-	-	-	-	-	-	-	-	-	1	-	1
Total	-	63	3	66	-	147	1	148	-	147	1	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	62	3	65	-	145	1	146	-	147	1	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	62	3	65	-	145	1	146	-	147	1	148
Week 24												
Low	-	-	-	-	-	1	-	1	-	-	-	-
Normal	-	60	3	63	-	144	1	145	-	147	1	148
High	-	1	-	1	-	-	-	-	-	-	-	-
Total	-	61	3	64	-	145	1	146	-	147	1	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（3/12）

pH

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	71	-	71	-	152	-	152	-	151	-	151
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	71	-	71	-	152	-	152	-	151	-	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	70	-	70	-	150	-	150	-	150	-	150
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	70	-	70	-	150	-	150	-	150	-	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	68	-	68	-	149	-	149	-	149	-	149
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	68	-	68	-	149	-	149	-	149	-	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	67	-	67	-	148	-	148	-	148	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	67	-	67	-	148	-	148	-	148	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（4/12）

pH

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	66	-	66	-	148	-	148	-	148	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	66	-	66	-	148	-	148	-	148	-	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	65	-	65	-	145	-	145	-	148	-	148
High	-	-	-	-	-	1	-	1	-	-	-	-
Total	-	65	-	65	-	146	-	146	-	148	-	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	64	-	64	-	146	-	146	-	148	-	148
High	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	64	-	64	-	146	-	146	-	148	-	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（5/12）

Glucose

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	48	3	51	-	101	31	132	-	96	26	122
High	-	3	17	20	-	2	18	20	-	4	25	29
Total	-	51	20	71	-	103	49	152	-	100	51	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	46	4	50	-	98	26	124	-	93	33	126
High	-	4	16	20	-	4	22	26	-	6	18	24
Total	-	50	20	70	-	102	48	150	-	99	51	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	45	5	50	-	98	29	127	-	94	27	121
High	-	5	13	18	-	4	18	22	-	5	23	28
Total	-	50	18	68	-	102	47	149	-	99	50	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	41	7	48	-	99	24	123	-	95	24	119
High	-	9	10	19	-	3	22	25	-	3	26	29
Total	-	50	17	67	-	102	46	148	-	98	50	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（6/12）

Glucose

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	41	5	46	-	95	21	116	-	95	31	126
High	-	9	11	20	-	7	25	32	-	3	19	22
Total	-	50	16	66	-	102	46	148	-	98	50	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	39	7	46	-	92	22	114	-	89	29	118
High	-	10	9	19	-	8	24	32	-	9	21	30
Total	-	49	16	65	-	100	46	146	-	98	50	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	40	5	45	-	92	19	111	-	89	29	118
High	-	8	11	19	-	8	27	35	-	9	21	30
Total	-	48	16	64	-	100	46	146	-	98	50	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（7/12）

Protein

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	53	3	56	-	120	14	134	-	117	8	125
High	-	6	9	15	-	6	12	18	-	4	22	26
Total	-	59	12	71	-	126	26	152	-	121	30	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	57	5	62	-	122	15	137	-	116	8	124
High	-	2	6	8	-	2	11	13	-	4	22	26
Total	-	59	11	70	-	124	26	150	-	120	30	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	55	2	57	-	116	15	131	-	109	11	120
High	-	2	9	11	-	7	11	18	-	10	19	29
Total	-	57	11	68	-	123	26	149	-	119	30	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	53	3	56	-	118	12	130	-	111	12	123
High	-	3	8	11	-	5	13	18	-	7	18	25
Total	-	56	11	67	-	123	25	148	-	118	30	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（8/12）

Protein

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	54	3	57	-	119	13	132	-	114	12	126
High	-	2	7	9	-	4	12	16	-	4	18	22
Total	-	56	10	66	-	123	25	148	-	118	30	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	53	4	57	-	113	14	127	-	109	11	120
High	-	2	6	8	-	8	11	19	-	9	19	28
Total	-	55	10	65	-	121	25	146	-	118	30	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	48	1	49	-	114	14	128	-	111	10	121
High	-	6	9	15	-	7	11	18	-	7	20	27
Total	-	54	10	64	-	121	25	146	-	118	30	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（9/12）

Occult Blood

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	66	2	68	-	138	5	143	-	132	7	139
High	-	1	2	3	-	2	7	9	-	4	8	12
Total	-	67	4	71	-	140	12	152	-	136	15	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	65	2	67	-	135	5	140	-	127	6	133
High	-	1	2	3	-	3	7	10	-	8	9	17
Total	-	66	4	70	-	138	12	150	-	135	15	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	64	2	66	-	136	5	141	-	127	9	136
High	-	-	2	2	-	1	7	8	-	7	6	13
Total	-	64	4	68	-	137	12	149	-	134	15	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	62	3	65	-	135	6	141	-	126	10	136
High	-	1	1	2	-	2	5	7	-	7	5	12
Total	-	63	4	67	-	137	11	148	-	133	15	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（10/12）

Occult Blood

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	59	2	61	-	134	3	137	-	127	7	134
High	-	3	2	5	-	3	8	11	-	6	8	14
Total	-	62	4	66	-	137	11	148	-	133	15	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	58	4	62	-	131	5	136	-	128	6	134
High	-	3	-	3	-	4	6	10	-	5	9	14
Total	-	61	4	65	-	135	11	146	-	133	15	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	57	2	59	-	128	4	132	-	127	5	132
High	-	3	2	5	-	7	7	14	-	6	10	16
Total	-	60	4	64	-	135	11	146	-	133	15	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（11/12）

Ketones

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 2												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	62	3	65	-	132	13	145	-	136	4	140
High	-	3	3	6	-	4	3	7	-	8	3	11
Total	-	65	6	71	-	136	16	152	-	144	7	151
Week 4												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	57	3	60	-	129	13	142	-	139	3	142
High	-	7	3	10	-	5	3	8	-	4	4	8
Total	-	64	6	70	-	134	16	150	-	143	7	150
Week 8												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	57	3	60	-	123	15	138	-	136	4	140
High	-	5	3	8	-	10	1	11	-	6	3	9
Total	-	62	6	68	-	133	16	149	-	142	7	149
Week 12												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	57	2	59	-	126	14	140	-	135	4	139
High	-	4	4	8	-	6	2	8	-	6	3	9
Total	-	61	6	67	-	132	16	148	-	141	7	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-30　尿検査の正異判定のクロス表（SYR-322-MET/CCT-001 試験）（12/12）

Ketones

	Week 0											
	Placebo (N=71)				QD (N=152)				BID (N=151)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 16												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	59	3	62	-	124	13	137	-	130	4	134
High	-	2	2	4	-	8	3	11	-	11	3	14
Total	-	61	5	66	-	132	16	148	-	141	7	148
Week 20												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	55	3	58	-	125	11	136	-	134	3	137
High	-	5	2	7	-	6	4	10	-	7	4	11
Total	-	60	5	65	-	131	15	146	-	141	7	148
Week 24												
Low	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	56	2	58	-	126	13	139	-	136	4	140
High	-	4	2	6	-	5	2	7	-	5	3	8
Total	-	60	4	64	-	131	15	146	-	141	7	148

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.2.4

表 2.7.4.7-付録-31　血液学的検査の評価時点別変化量（SYR-322/CCT-006 試験）（1/7）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
RBC ($x10^4/\mu L$)	Week 2	Placebo	100	-2.9	17.55	-45	-14.0	-2.0	11.0	35
		12.5 mg	92	-5.8	19.42	-61	-20.0	-8.5	10.5	44
		25 mg	96	-10.5	17.79	-67	-21.5	-8.0	1.0	26
	Week 4	Placebo	100	-2.2	18.33	-56	-10.5	-1.0	7.0	71
		12.5 mg	90	-3.2	19.69	-48	-17.0	-4.0	7.0	46
		25 mg	95	-7.1	19.34	-63	-18.0	-6.0	3.0	48
	Week 8	Placebo	100	-0.9	17.90	-53	-11.5	-1.0	11.0	35
		12.5 mg	91	-3.6	22.96	-46	-18.0	-7.0	8.0	78
		25 mg	94	-3.8	19.47	-81	-15.0	-4.0	8.0	49
	Week 12	Placebo	100	0.6	18.95	-44	-12.0	1.0	13.5	51
		12.5 mg	91	-0.3	24.87	-70	-15.0	0.0	11.0	78
		25 mg	93	0.3	21.61	-62	-12.0	1.0	15.0	57
WBC ($/\mu L$)	Week 2	Placebo	100	234.0	1142.41	-2400	-400.0	100.0	800.0	4200
		12.5 mg	92	-77.2	1363.58	-4500	-750.0	0.0	550.0	4500
		25 mg	96	177.1	1240.67	-5400	-400.0	100.0	600.0	5400
	Week 4	Placebo	100	-33.0	1319.55	-4600	-600.0	-200.0	500.0	4900
		12.5 mg	90	-70.0	1534.29	-5700	-700.0	-200.0	500.0	5100
		25 mg	95	151.6	1337.34	-5400	-500.0	100.0	700.0	5100
	Week 8	Placebo	100	-4.0	1194.17	-3000	-900.0	-100.0	600.0	2700
		12.5 mg	91	-1.1	1299.96	-3700	-700.0	0.0	700.0	6600
		25 mg	94	368.1	1519.49	-4300	-300.0	250.0	1000.0	5900
	Week 12	Placebo	100	111.0	1244.05	-3000	-700.0	100.0	850.0	5300
		12.5 mg	91	267.0	1463.41	-5700	-700.0	200.0	1000.0	4700
		25 mg	93	247.3	1770.45	-5100	-600.0	200.0	800.0	11600

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-31　血液学的検査の評価時点別変化量（SYR-322/CCT-006 試験）（2/7）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Hemoglobin (g/dL)	Week 2	Placebo	100	-0.05	0.532	-1.3	-0.40	0.00	0.30	1.2
		12.5 mg	92	-0.16	0.600	-1.8	-0.60	-0.20	0.35	1.2
		25 mg	96	-0.30	0.579	-2.3	-0.70	-0.25	0.00	1.1
	Week 4	Placebo	100	-0.07	0.571	-1.7	-0.40	0.00	0.20	2.2
		12.5 mg	90	-0.10	0.607	-1.4	-0.50	-0.10	0.30	1.4
		25 mg	95	-0.22	0.620	-2.3	-0.50	-0.30	0.10	1.6
	Week 8	Placebo	100	-0.05	0.541	-1.6	-0.40	0.00	0.30	1.0
		12.5 mg	91	-0.17	0.683	-1.4	-0.70	-0.30	0.20	2.2
		25 mg	94	-0.18	0.599	-2.2	-0.50	-0.20	0.20	1.4
	Week 12	Placebo	100	-0.05	0.576	-1.2	-0.50	-0.05	0.35	1.9
		12.5 mg	91	-0.15	0.742	-2.1	-0.70	-0.20	0.40	1.8
		25 mg	93	-0.14	0.672	-2.2	-0.60	-0.10	0.30	1.4
Hematocrit (%)	Week 2	Placebo	100	-0.19	1.667	-4.1	-1.50	-0.15	1.10	3.5
		12.5 mg	92	-0.57	1.925	-5.1	-1.90	-0.60	0.95	4.5
		25 mg	96	-1.01	1.765	-6.7	-2.05	-0.75	0.20	3.2
	Week 4	Placebo	100	-0.27	1.798	-6.5	-1.25	-0.15	0.60	6.7
		12.5 mg	90	-0.35	1.831	-4.6	-1.50	-0.45	0.70	3.7
		25 mg	95	-0.76	1.907	-6.0	-1.90	-0.50	0.20	4.1
	Week 8	Placebo	100	-0.22	1.742	-5.1	-1.40	-0.10	0.85	4.0
		12.5 mg	91	-0.55	2.207	-5.0	-2.00	-0.80	0.50	9.1
		25 mg	94	-0.61	1.871	-7.2	-1.60	-0.60	0.50	4.9
	Week 12	Placebo	100	-0.21	1.780	-4.7	-1.35	0.05	1.10	4.9
		12.5 mg	91	-0.38	2.255	-6.6	-1.70	-0.10	0.70	5.9
		25 mg	93	-0.35	1.935	-5.8	-1.60	-0.40	1.10	4.5

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-31　血液学的検査の評価時点別変化量（SYR-322/CCT-006 試験）（3/7）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Platelet Count (x10^4/μL)	Week 2	Placebo	98	0.23	2.958	-11.0	-1.40	0.10	1.80	9.4
		12.5 mg	89	0.04	3.120	-12.4	-1.50	-0.20	1.20	12.5
		25 mg	95	0.64	2.903	-5.8	-1.10	0.60	2.10	8.8
	Week 4	Placebo	99	0.06	3.115	-8.5	-1.40	0.10	1.60	9.0
		12.5 mg	89	0.02	2.717	-8.6	-1.50	0.20	1.40	8.9
		25 mg	94	0.29	2.537	-5.4	-1.50	0.20	1.70	9.8
	Week 8	Placebo	97	-0.33	3.056	-10.0	-2.40	-0.30	1.60	8.0
		12.5 mg	90	-0.18	3.050	-11.3	-2.00	0.10	1.40	7.6
		25 mg	93	0.19	2.957	-5.4	-1.60	0.00	1.50	17.5
	Week 12	Placebo	99	-0.13	3.040	-10.4	-1.80	0.00	1.70	9.3
		12.5 mg	90	-0.50	3.049	-13.7	-2.10	-0.50	0.90	6.4
		25 mg	91	0.03	2.522	-8.5	-1.20	-0.10	1.70	7.0
Neutrophils (%)	Week 2	Placebo	100	0.48	7.069	-16.5	-4.00	-0.20	4.60	23.0
		12.5 mg	92	2.05	7.441	-21.3	-2.10	2.15	6.15	26.2
		25 mg	96	1.46	5.680	-11.8	-2.65	1.85	5.50	16.0
	Week 4	Placebo	100	1.03	8.216	-25.7	-3.35	0.65	4.70	30.5
		12.5 mg	90	2.10	8.939	-22.2	-2.40	1.70	6.90	32.0
		25 mg	95	0.86	6.943	-14.2	-4.20	1.00	5.80	15.1
	Week 8	Placebo	99	-0.59	6.668	-22.9	-4.10	-0.20	3.80	13.4
		12.5 mg	91	1.73	7.118	-14.9	-2.40	1.30	7.80	21.1
		25 mg	94	1.72	7.202	-15.5	-3.30	0.50	5.50	23.0
	Week 12	Placebo	100	0.26	7.370	-26.1	-3.55	0.45	4.50	23.7
		12.5 mg	91	2.55	7.857	-20.1	-2.00	3.20	6.50	24.8
		25 mg	93	1.26	6.466	-19.4	-2.10	1.00	5.30	20.9

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-31　血液学的検査の評価時点別変化量（SYR-322/CCT-006 試験）（4/7）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Eosinophils (%)	Week 2	Placebo	100	-0.27	1.234	-4.6	-0.60	-0.20	0.30	3.5
		12.5 mg	92	-0.24	1.647	-4.7	-0.85	-0.25	0.30	6.5
		25 mg	96	-0.04	1.212	-3.7	-0.60	-0.20	0.35	5.5
	Week 4	Placebo	100	-0.20	1.236	-4.8	-0.65	-0.15	0.35	3.9
		12.5 mg	90	-0.08	1.786	-7.4	-1.00	-0.20	0.50	7.1
		25 mg	95	0.11	1.251	-2.6	-0.50	0.00	0.50	7.0
	Week 8	Placebo	99	0.12	1.389	-3.6	-0.50	0.00	0.80	6.2
		12.5 mg	91	0.01	1.826	-7.7	-1.00	-0.30	0.60	5.2
		25 mg	94	0.19	1.710	-3.4	-0.60	0.00	0.60	8.9
	Week 12	Placebo	100	0.29	1.689	-4.1	-0.45	0.00	0.85	6.3
		12.5 mg	91	-0.10	1.946	-6.4	-1.10	-0.30	0.40	8.9
		25 mg	93	0.37	1.520	-3.3	-0.40	0.20	0.60	9.2
Monocytes (%)	Week 2	Placebo	100	0.05	1.632	-9.8	-0.75	0.20	1.00	3.0
		12.5 mg	92	0.40	1.442	-2.9	-0.60	0.30	1.10	4.7
		25 mg	96	0.14	1.539	-3.0	-0.80	-0.10	0.90	6.5
	Week 4	Placebo	100	0.04	1.539	-9.0	-0.55	0.20	0.95	4.2
		12.5 mg	90	0.18	1.243	-3.1	-0.50	0.10	1.00	3.5
		25 mg	95	0.43	1.861	-4.0	-0.60	0.30	1.30	10.5
	Week 8	Placebo	99	0.12	1.632	-9.9	-0.50	0.20	1.00	4.3
		12.5 mg	91	0.21	1.283	-3.4	-0.60	0.30	1.00	3.7
		25 mg	94	0.20	1.410	-4.0	-0.60	0.20	0.90	3.5
	Week 12	Placebo	100	0.07	1.681	-9.2	-0.60	0.10	1.00	4.3
		12.5 mg	91	0.02	1.251	-5.5	-0.80	0.10	0.70	2.8
		25 mg	93	0.34	1.508	-3.9	-0.30	0.50	0.90	3.9

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-31　血液学的検査の評価時点別変化量（SYR-322/CCT-006 試験）（5/7）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Lymphocytes (%)	Week 2	Placebo	100	-0.25	6.116	-16.0	-3.75	0.20	3.50	15.5
		12.5 mg	92	-2.18	6.701	-24.5	-5.40	-1.95	1.00	19.0
		25 mg	96	-1.59	4.936	-14.2	-4.75	-1.60	1.70	10.4
	Week 4	Placebo	100	-0.81	7.230	-28.7	-3.75	-0.70	3.15	20.5
		12.5 mg	90	-2.19	8.147	-28.3	-7.10	-1.90	2.00	19.9
		25 mg	95	-1.39	5.846	-14.9	-6.00	-0.90	2.20	12.0
	Week 8	Placebo	99	0.42	6.028	-14.8	-4.20	0.50	3.30	20.1
		12.5 mg	91	-1.88	6.238	-20.2	-5.70	-2.00	1.50	12.8
		25 mg	94	-2.06	6.165	-20.8	-5.90	-1.90	2.50	11.2
	Week 12	Placebo	100	-0.53	6.882	-23.4	-4.35	-0.75	3.10	22.7
		12.5 mg	91	-2.46	6.924	-24.2	-5.80	-3.00	1.70	19.2
		25 mg	93	-1.94	5.628	-21.6	-5.00	-1.60	1.50	14.9
Basophils (%)	Week 2	Placebo	100	-0.01	0.511	-2.1	-0.20	0.00	0.20	1.3
		12.5 mg	92	-0.04	0.544	-2.4	-0.20	0.00	0.20	1.2
		25 mg	96	0.04	0.533	-2.7	-0.20	0.05	0.30	1.8
	Week 4	Placebo	100	-0.07	0.482	-2.0	-0.20	0.00	0.10	1.4
		12.5 mg	90	-0.01	0.555	-1.8	-0.20	0.00	0.10	2.1
		25 mg	95	-0.01	0.506	-2.3	-0.20	0.00	0.20	2.0
	Week 8	Placebo	99	-0.07	0.509	-1.5	-0.20	0.00	0.10	1.5
		12.5 mg	91	-0.07	0.458	-2.0	-0.20	0.00	0.10	1.1
		25 mg	94	-0.04	0.487	-2.3	-0.20	0.00	0.20	1.0
	Week 12	Placebo	100	-0.10	0.462	-2.1	-0.30	-0.05	0.15	1.0
		12.5 mg	91	-0.01	0.574	-1.9	-0.30	0.00	0.20	2.3
		25 mg	93	-0.02	0.466	-2.0	-0.20	0.00	0.20	1.5

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-31　血液学的検査の評価時点別変化量（SYR-322/CCT-006 試験）（6/7）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
MCV (fL)	Week 2	Placebo	100	0.1	1.10	-2	-0.5	0.0	1.0	3
		12.5 mg	92	-0.1	1.04	-3	-1.0	0.0	0.0	3
		25 mg	96	-0.1	1.06	-3	-1.0	0.0	1.0	2
	Week 4	Placebo	100	-0.1	1.17	-3	-1.0	0.0	1.0	2
		12.5 mg	90	-0.2	1.06	-4	-1.0	0.0	0.0	2
		25 mg	95	-0.2	1.23	-4	-1.0	0.0	0.0	4
	Week 8	Placebo	100	-0.3	1.25	-3	-1.0	-0.5	0.5	5
		12.5 mg	91	-0.5	1.29	-6	-1.0	-1.0	0.0	3
		25 mg	94	-0.6	1.36	-5	-1.0	-0.5	0.0	3
	Week 12	Placebo	100	-0.5	1.30	-3	-1.0	-1.0	0.0	4
		12.5 mg	91	-0.8	1.46	-7	-2.0	-1.0	0.0	2
		25 mg	93	-0.8	1.31	-5	-2.0	-1.0	0.0	4
MCH (pg/cell)	Week 2	Placebo	100	0.07	0.357	-0.7	-0.20	0.00	0.30	0.9
		12.5 mg	92	0.04	0.397	-1.3	-0.20	0.00	0.30	1.4
		25 mg	96	0.04	0.384	-0.9	-0.20	0.10	0.30	1.0
	Week 4	Placebo	100	-0.02	0.328	-0.8	-0.25	0.00	0.20	0.8
		12.5 mg	90	-0.03	0.357	-1.4	-0.20	0.00	0.20	0.7
		25 mg	95	-0.01	0.388	-1.4	-0.20	0.00	0.30	0.7
	Week 8	Placebo	100	-0.04	0.436	-1.0	-0.30	0.00	0.20	1.0
		12.5 mg	91	-0.13	0.433	-1.5	-0.40	-0.10	0.20	0.8
		25 mg	94	-0.16	0.425	-1.5	-0.40	-0.10	0.10	1.0
	Week 12	Placebo	100	-0.16	0.505	-2.1	-0.40	-0.10	0.15	0.8
		12.5 mg	91	-0.32	0.510	-2.1	-0.60	-0.30	0.00	0.9
		25 mg	93	-0.32	0.516	-2.2	-0.60	-0.30	-0.10	0.9

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-31　血液学的検査の評価時点別変化量（SYR-322/CCT-006 試験）（7/7）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
MCHC (%)	Week 2	Placebo	100	0.03	0.552	-1.2	-0.30	0.00	0.40	1.3
		12.5 mg	92	0.10	0.614	-1.3	-0.30	0.00	0.55	2.0
		25 mg	96	0.09	0.579	-1.1	-0.30	0.00	0.50	1.6
	Week 4	Placebo	100	0.04	0.535	-1.1	-0.40	0.05	0.40	1.4
		12.5 mg	90	0.05	0.549	-1.8	-0.20	0.10	0.40	1.5
		25 mg	95	0.08	0.560	-1.3	-0.30	0.10	0.40	1.7
	Week 8	Placebo	100	0.07	0.599	-1.4	-0.35	0.10	0.50	1.4
		12.5 mg	91	0.06	0.573	-1.7	-0.30	0.20	0.40	1.4
		25 mg	94	0.04	0.558	-1.4	-0.30	0.05	0.40	1.3
	Week 12	Placebo	100	0.04	0.675	-2.0	-0.40	0.10	0.45	1.7
		12.5 mg	91	-0.04	0.676	-1.6	-0.40	0.00	0.50	1.8
		25 mg	93	-0.05	0.576	-1.4	-0.40	0.00	0.30	1.8

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（1/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
RBC	Week 2	Lower	4	1	-	5	8	6	-	14	5	5	-	10
		Normal	1	92	-	93	2	73	2	77	2	83	1	86
		Upper	-	-	2	2	-	1	-	1	-	-	-	-
		Total	5	93	2	100	10	80	2	92	7	88	1	96
	Week 4	Lower	3	4	-	7	8	2	-	10	6	4	-	10
		Normal	2	88	-	90	2	76	1	79	1	81	1	83
		Upper	-	1	2	3	-	-	1	1	-	2	-	2
		Total	5	93	2	100	10	78	2	90	7	87	1	95
	Week 8	Lower	3	2	-	5	6	5	-	11	6	3	-	9
		Normal	2	89	1	92	4	73	1	78	1	82	1	84
		Upper	-	2	1	3	-	1	1	2	-	1	-	1
		Total	5	93	2	100	10	79	2	91	7	86	1	94
	Week 12	Lower	3	1	-	4	6	5	-	11	5	1	-	6
		Normal	2	89	-	91	4	74	-	78	2	81	1	84
		Upper	-	3	2	5	-	-	2	2	-	3	-	3
		Total	5	93	2	100	10	79	2	91	7	85	1	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（2/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
WBC	Week 2	Lower	-	-	-	-	1	-	-	1	-	1	-	1
		Normal	-	84	3	87	-	73	6	79	1	80	3	84
		Upper	-	7	6	13	-	5	7	12	-	5	6	11
		Total	-	91	9	100	1	78	13	92	1	86	9	96
	Week 4	Lower	-	-	-	-	-	1	-	1	-	-	-	-
		Normal	-	84	5	89	1	72	6	79	1	80	4	85
		Upper	-	7	4	11	-	3	7	10	-	5	5	10
		Total	-	91	9	100	1	76	13	90	1	85	9	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	88	3	91	1	71	7	79	1	78	5	84
		Upper	-	3	6	9	-	6	6	12	-	6	4	10
		Total	-	91	9	100	1	77	13	91	1	84	9	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	84	6	90	1	71	4	76	1	76	3	80
		Upper	-	7	3	10	-	6	9	15	-	7	6	13
		Total	-	91	9	100	1	77	13	91	1	83	9	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（3/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Hemoglobin	Week 2	Lower	2	1	-	3	2	4	-	6	3	3	-	6
		Normal	1	91	1	93	6	77	2	85	1	85	2	88
		Upper	-	1	3	4	-	1	-	1	-	1	1	2
		Total	3	93	4	100	8	82	2	92	4	89	3	96
	Week 4	Lower	2	2	-	4	4	3	-	7	3	4	-	7
		Normal	1	90	2	93	4	76	1	81	1	82	2	85
		Upper	-	1	2	3	-	1	1	2	-	2	1	3
		Total	3	93	4	100	8	80	2	90	4	88	3	95
	Week 8	Lower	3	1	-	4	3	4	-	7	2	4	-	6
		Normal	-	91	1	92	5	75	1	81	2	82	2	86
		Upper	-	1	3	4	-	2	1	3	-	1	1	2
		Total	3	93	4	100	8	81	2	91	4	87	3	94
	Week 12	Lower	2	-	-	2	3	8	-	11	3	1	-	4
		Normal	1	91	3	95	5	71	1	77	1	85	1	87
		Upper	-	2	1	3	-	2	1	3	-	-	2	2
		Total	3	93	4	100	8	81	2	91	4	86	3	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（4/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Hematocrit	Week 2	Lower	4	-	-	4	5	5	-	10	4	3	-	7
		Normal	1	91	-	92	5	74	2	81	1	86	-	87
		Upper	-	2	2	4	-	1	-	1	-	1	1	2
		Total	5	93	2	100	10	80	2	92	5	90	1	96
	Week 4	Lower	5	3	-	8	6	6	-	12	4	3	-	7
		Normal	-	88	1	89	4	72	2	78	1	85	-	86
		Upper	-	2	1	3	-	-	-	-	-	1	1	2
		Total	5	93	2	100	10	78	2	90	5	89	1	95
	Week 8	Lower	3	2	-	5	7	4	-	11	3	3	-	6
		Normal	2	90	1	93	3	74	2	79	2	85	-	87
		Upper	-	1	1	2	-	1	-	1	-	-	1	1
		Total	5	93	2	100	10	79	2	91	5	88	1	94
	Week 12	Lower	2	3	-	5	6	7	-	13	4	3	-	7
		Normal	3	88	2	93	4	72	2	78	1	84	-	85
		Upper	-	2	-	2	-	-	-	-	-	-	1	1
		Total	5	93	2	100	10	79	2	91	5	87	1	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（5/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Platelet Count	Week 2	Lower	1	-	-	1	-	-	-	-	1	-	-	1
		Normal	-	88	2	90	-	73	3	76	2	82	2	86
		Upper	-	2	5	7	-	4	9	13	-	4	4	8
		Total	1	90	7	98	-	77	12	89	3	86	6	95
	Week 4	Lower	1	-	-	1	-	-	-	-	1	-	-	1
		Normal	-	87	4	91	-	74	2	76	2	82	1	85
		Upper	-	4	3	7	-	3	10	13	-	3	5	8
		Total	1	91	7	99	-	77	12	89	3	85	6	94
	Week 8	Lower	1	-	-	1	-	1	-	1	1	-	-	1
		Normal	-	87	4	91	-	73	4	77	1	82	2	85
		Upper	-	2	3	5	-	4	8	12	-	3	4	7
		Total	1	89	7	97	-	78	12	90	2	85	6	93
	Week 12	Lower	1	-	-	1	-	-	-	-	1	1	-	2
		Normal	-	87	3	90	-	75	5	80	1	81	2	84
		Upper	-	4	4	8	-	3	7	10	-	2	3	5
		Total	1	91	7	99	-	78	12	90	2	84	5	91

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（6/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Neutrophils	Week 2	Lower	1	1	-	2	-	-	-	-	2	-	-	2
		Normal	1	96	-	97	3	87	1	91	1	89	1	91
		Upper	-	1	-	1	-	1	-	1	-	1	2	3
		Total	2	98	-	100	3	88	1	92	3	90	3	96
	Week 4	Lower	1	2	-	3	-	-	-	-	2	-	-	2
		Normal	1	93	-	94	3	84	1	88	1	88	3	92
		Upper	-	3	-	3	-	2	-	2	-	1	-	1
		Total	2	98	-	100	3	86	1	90	3	89	3	95
	Week 8	Lower	1	1	-	2	-	1	-	1	2	-	-	2
		Normal	1	96	-	97	3	84	1	88	1	86	3	90
		Upper	-	-	-	-	-	2	-	2	-	2	-	2
		Total	2	97	-	99	3	87	1	91	3	88	3	94
	Week 12	Lower	1	1	-	2	-	-	-	-	2	-	-	2
		Normal	1	97	-	98	3	85	1	89	1	85	3	89
		Upper	-	-	-	-	-	2	-	2	-	2	-	2
		Total	2	98	-	100	3	87	1	91	3	87	3	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（7/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Eosinophils	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	95	3	98	-	87	2	89	-	95	1	96
		Upper	-	1	1	2	-	1	2	3	-	-	-	-
		Total	-	96	4	100	-	88	4	92	-	95	1	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	95	2	97	-	85	2	87	-	93	-	93
		Upper	-	1	2	3	-	1	2	3	-	1	1	2
		Total	-	96	4	100	-	86	4	90	-	94	1	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	93	3	96	-	85	3	88	-	90	1	91
		Upper	-	2	1	3	-	2	1	3	-	3	-	3
		Total	-	95	4	99	-	87	4	91	-	93	1	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	91	2	93	-	84	2	86	-	91	1	92
		Upper	-	5	2	7	-	3	2	5	-	1	-	1
		Total	-	96	4	100	-	87	4	91	-	92	1	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（8/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Monocytes	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	99	1	100	-	90	-	90	-	96	-	96
		Upper	-	-	-	-	-	2	-	2	-	-	-	-
		Total	-	99	1	100	-	92	-	92	-	96	-	96
	Week 4	Lower	-	1	-	1	-	-	-	-	-	-	-	-
		Normal	-	98	1	99	-	89	-	89	-	94	-	94
		Upper	-	-	-	-	-	1	-	1	-	1	-	1
		Total	-	99	1	100	-	90	-	90	-	95	-	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	98	1	99	-	90	-	90	-	94	-	94
		Upper	-	-	-	-	-	1	-	1	-	-	-	-
		Total	-	98	1	99	-	91	-	91	-	94	-	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	98	1	99	-	91	-	91	-	92	-	92
		Upper	-	1	-	1	-	-	-	-	-	1	-	1
		Total	-	99	1	100	-	91	-	91	-	93	-	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（9/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Lymphocytes	Week 2	Lower	-	2	-	2	-	1	-	1	2	2	-	4
		Normal	1	92	3	96	2	85	4	91	1	87	2	90
		Upper	-	-	2	2	-	-	-	-	-	-	2	2
		Total	1	94	5	100	2	86	4	92	3	89	4	96
	Week 4	Lower	-	3	-	3	-	2	-	2	1	2	-	3
		Normal	1	90	2	93	2	82	4	88	2	86	3	91
		Upper	-	1	3	4	-	-	-	-	-	-	1	1
		Total	1	94	5	100	2	84	4	90	3	88	4	95
	Week 8	Lower	-	2	-	2	-	3	-	3	1	5	-	6
		Normal	1	87	4	92	2	82	4	88	2	81	2	85
		Upper	-	4	1	5	-	-	-	-	-	1	2	3
		Total	1	93	5	99	2	85	4	91	3	87	4	94
	Week 12	Lower	-	-	-	-	-	3	-	3	1	1	-	2
		Normal	1	92	4	97	2	82	4	88	2	85	2	89
		Upper	-	2	1	3	-	-	-	-	-	-	2	2
		Total	1	94	5	100	2	85	4	91	3	86	4	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（10/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Basophils	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	99	1	100	-	90	2	92	-	94	1	95
		Upper	-	-	-	-	-	-	-	-	-	1	-	1
		Total	-	99	1	100	-	90	2	92	-	95	1	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	99	1	100	-	87	2	89	-	94	1	95
		Upper	-	-	-	-	-	1	-	1	-	-	-	-
		Total	-	99	1	100	-	88	2	90	-	94	1	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	98	1	99	-	89	2	91	-	93	1	94
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	-	98	1	99	-	89	2	91	-	93	1	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	99	1	100	-	88	2	90	-	92	1	93
		Upper	-	-	-	-	-	1	-	1	-	-	-	-
		Total	-	99	1	100	-	89	2	91	-	92	1	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（11/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
MCV	Week 2	Lower	5	-	-	5	1	1	-	2	4	-	-	4
		Normal	-	95	-	95	-	88	-	88	-	91	1	92
		Upper	-	-	-	-	-	-	2	2	-	-	-	-
		Total	5	95	-	100	1	89	2	92	4	91	1	96
	Week 4	Lower	4	1	-	5	1	1	-	2	4	-	-	4
		Normal	1	93	-	94	-	86	-	86	-	90	-	90
		Upper	-	1	-	1	-	-	2	2	-	-	1	1
		Total	5	95	-	100	1	87	2	90	4	90	1	95
	Week 8	Lower	4	1	-	5	1	2	-	3	3	-	-	3
		Normal	1	93	-	94	-	86	-	86	1	89	-	90
		Upper	-	1	-	1	-	-	2	2	-	-	1	1
		Total	5	95	-	100	1	88	2	91	4	89	1	94
	Week 12	Lower	5	2	-	7	1	3	-	4	4	-	-	4
		Normal	-	93	-	93	-	85	1	86	-	88	1	89
		Upper	-	-	-	-	-	-	1	1	-	-	-	-
		Total	5	95	-	100	1	88	2	91	4	88	1	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（12/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
MCH	Week 2	Lower	4	-	-	4	-	-	-	-	3	-	-	3
		Normal	-	86	1	87	-	86	1	87	-	88	-	88
		Upper	-	-	9	9	-	-	5	5	-	1	4	5
		Total	4	86	10	100	-	86	6	92	3	89	4	96
	Week 4	Lower	4	-	-	4	-	-	-	-	3	1	-	4
		Normal	-	86	1	87	-	84	2	86	-	86	-	86
		Upper	-	-	9	9	-	-	4	4	-	1	4	5
		Total	4	86	10	100	-	84	6	90	3	88	4	95
	Week 8	Lower	4	-	-	4	-	-	-	-	3	1	-	4
		Normal	-	86	1	87	-	85	2	87	-	85	1	86
		Upper	-	-	9	9	-	-	4	4	-	1	3	4
		Total	4	86	10	100	-	85	6	91	3	87	4	94
	Week 12	Lower	4	-	-	4	-	1	-	1	3	1	-	4
		Normal	-	86	1	87	-	84	2	86	-	84	1	85
		Upper	-	-	9	9	-	-	4	4	-	1	3	4
		Total	4	86	10	100	-	85	6	91	3	86	4	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-32　血液学的検査の正異判定のクロス表（SYR-322/CCT-006 試験）（13/13）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
MCHC	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	91	7	98	-	82	4	86	-	83	4	87
		Upper	-	1	1	2	-	5	1	6	-	6	3	9
		Total	-	92	8	100	-	87	5	92	-	89	7	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	90	7	97	-	82	3	85	-	79	3	82
		Upper	-	2	1	3	-	3	2	5	-	9	4	13
		Total	-	92	8	100	-	85	5	90	-	88	7	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	86	6	92	-	84	4	88	-	80	4	84
		Upper	-	6	2	8	-	2	1	3	-	7	3	10
		Total	-	92	8	100	-	86	5	91	-	87	7	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	89	8	97	-	84	4	88	-	85	7	92
		Upper	-	3	-	3	-	2	1	3	-	1	-	1
		Total	-	92	8	100	-	86	5	91	-	86	7	93

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-33　血液生化学検査の評価時点別変化量（SYR-322/CCT-006 試験）（1/10）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
ALT (IU/L)	Week 2	Placebo	100	1.2	8.24	-17	-3.0	0.0	5.0	31
		12.5 mg	92	0.7	8.58	-18	-3.0	0.0	3.5	40
		25 mg	96	1.0	10.11	-26	-3.0	-1.0	3.0	48
	Week 4	Placebo	100	0.9	9.47	-24	-3.0	1.0	5.0	48
		12.5 mg	90	1.8	11.95	-21	-3.0	-0.5	4.0	62
		25 mg	95	0.1	6.77	-25	-3.0	1.0	4.0	21
	Week 8	Placebo	100	-1.8	10.66	-49	-7.0	-1.0	4.5	22
		12.5 mg	91	1.0	10.54	-30	-4.0	0.0	4.0	50
		25 mg	94	0.5	13.39	-44	-5.0	0.0	4.0	89
	Week 12	Placebo	100	-2.2	13.09	-56	-6.5	-2.0	2.5	54
		12.5 mg	91	1.0	11.28	-28	-4.0	0.0	3.0	49
		25 mg	94	-0.6	9.26	-47	-4.0	0.0	3.0	38
AST (IU/L)	Week 2	Placebo	100	0.9	7.03	-14	-3.0	0.0	3.0	29
		12.5 mg	92	1.7	7.24	-11	-1.0	0.5	3.0	41
		25 mg	96	1.6	8.42	-25	-2.0	0.0	3.5	32
	Week 4	Placebo	100	0.8	7.78	-21	-2.0	0.0	4.0	51
		12.5 mg	90	2.2	8.00	-16	-1.0	1.0	4.0	45
		25 mg	95	0.4	6.80	-29	-1.0	1.0	3.0	24
	Week 8	Placebo	100	-0.7	7.26	-24	-3.0	0.0	2.0	24
		12.5 mg	91	1.0	6.44	-16	-2.0	1.0	3.0	41
		25 mg	94	1.3	11.64	-25	-2.0	1.0	3.0	97
	Week 12	Placebo	100	-1.1	9.72	-33	-4.0	-1.0	2.0	52
		12.5 mg	91	1.3	6.87	-20	-2.0	0.0	3.0	27
		25 mg	94	0.1	8.82	-56	-2.0	0.0	3.0	35

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-33　血液生化学検査の評価時点別変化量（SYR-322/CCT-006 試験）（2/10）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
GGT (IU/L)	Week 2	Placebo	100	3.1	22.33	-39	-3.0	1.0	5.0	150
		12.5 mg	92	-0.6	19.30	-74	-5.0	-0.5	2.5	128
		25 mg	96	-3.0	10.18	-59	-4.0	-2.0	1.0	17
	Week 4	Placebo	100	2.1	23.33	-49	-4.0	0.0	4.0	145
		12.5 mg	90	-3.2	14.45	-65	-5.0	-1.0	3.0	26
		25 mg	95	-2.6	11.04	-50	-4.0	-2.0	2.0	25
	Week 8	Placebo	100	-1.2	21.95	-82	-6.0	-1.0	2.5	152
		12.5 mg	91	-1.4	13.93	-47	-5.0	-1.0	4.0	34
		25 mg	94	-1.6	10.39	-38	-5.0	-1.0	4.0	24
	Week 12	Placebo	100	-2.1	25.30	-130	-6.0	-1.0	4.0	118
		12.5 mg	91	-1.4	21.79	-60	-5.0	-1.0	4.0	127
		25 mg	94	-1.6	10.35	-34	-6.0	-1.0	3.0	26
Alkaline Phosphatase (IU/L)	Week 2	Placebo	100	-2.5	26.58	-97	-16.0	-1.0	13.5	57
		12.5 mg	92	-8.0	27.25	-107	-21.5	-4.0	7.5	61
		25 mg	96	-19.4	41.15	-310	-29.0	-10.5	-0.5	38
	Week 4	Placebo	100	-4.2	25.02	-91	-15.5	-2.5	9.5	80
		12.5 mg	90	-10.2	33.55	-171	-23.0	-5.0	9.0	62
		25 mg	95	-11.2	34.67	-149	-22.0	-8.0	10.0	107
	Week 8	Placebo	100	-7.0	26.31	-90	-19.0	-8.5	5.5	80
		12.5 mg	91	-19.0	36.11	-195	-39.0	-15.0	0.0	60
		25 mg	94	-19.8	47.20	-318	-30.0	-13.5	2.0	77
	Week 12	Placebo	100	-7.8	31.16	-100	-23.0	-6.5	7.0	64
		12.5 mg	91	-16.8	32.67	-165	-33.0	-14.0	4.0	88
		25 mg	94	-21.3	40.57	-280	-33.0	-16.0	-3.0	83

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-33　血液生化学検査の評価時点別変化量（SYR-322/CCT-006 試験）（3/10）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Bilirubin Total (mg/dL)	Week 2	Placebo	100	0.05	0.245	-0.5	-0.10	0.00	0.20	1.6
		12.5 mg	92	-0.01	0.179	-0.4	-0.10	0.00	0.10	0.4
		25 mg	96	-0.03	0.240	-0.9	-0.20	0.00	0.10	0.6
	Week 4	Placebo	100	0.02	0.202	-0.5	-0.10	0.00	0.10	0.9
		12.5 mg	90	-0.01	0.202	-0.6	-0.10	0.00	0.10	0.5
		25 mg	95	-0.03	0.238	-0.7	-0.20	0.00	0.10	0.5
	Week 8	Placebo	100	0.02	0.239	-0.7	-0.10	0.00	0.20	1.0
		12.5 mg	91	-0.02	0.206	-0.5	-0.20	0.00	0.10	0.6
		25 mg	94	0.02	0.302	-0.7	-0.10	0.00	0.20	1.4
	Week 12	Placebo	100	0.03	0.213	-0.5	-0.10	0.00	0.20	0.8
		12.5 mg	91	-0.01	0.203	-0.8	-0.10	0.00	0.10	0.5
		25 mg	94	0.02	0.223	-0.4	-0.10	0.00	0.20	0.8
Protein Total (g/dL)	Week 2	Placebo	100	0.01	0.406	-1.2	-0.30	0.00	0.20	1.4
		12.5 mg	92	-0.02	0.347	-0.7	-0.30	0.00	0.30	0.6
		25 mg	96	-0.11	0.387	-1.4	-0.30	-0.10	0.10	0.9
	Week 4	Placebo	100	-0.00	0.354	-0.9	-0.25	0.00	0.20	0.9
		12.5 mg	90	0.03	0.401	-0.9	-0.20	0.05	0.30	1.2
		25 mg	95	0.01	0.407	-1.1	-0.20	0.00	0.20	1.4
	Week 8	Placebo	100	-0.07	0.405	-1.5	-0.30	0.00	0.20	1.0
		12.5 mg	91	-0.06	0.433	-1.1	-0.30	-0.10	0.20	1.3
		25 mg	94	-0.00	0.494	-1.4	-0.30	0.00	0.20	1.7
	Week 12	Placebo	100	-0.06	0.463	-1.9	-0.30	-0.10	0.20	1.2
		12.5 mg	91	0.08	0.530	-1.1	-0.20	0.00	0.30	2.1
		25 mg	94	0.05	0.420	-1.2	-0.10	0.10	0.30	1.3

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-33　血液生化学検査の評価時点別変化量（SYR-322/CCT-006 試験）（4/10）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Albumin (g/dL)	Week 2	Placebo	100	0.01	0.227	-0.5	-0.10	0.00	0.20	0.9
		12.5 mg	92	0.00	0.199	-0.4	-0.15	0.00	0.10	0.5
		25 mg	96	-0.05	0.234	-0.8	-0.20	0.00	0.10	0.5
	Week 4	Placebo	100	0.02	0.204	-0.4	-0.10	0.05	0.20	0.4
		12.5 mg	90	0.04	0.245	-0.5	-0.10	0.00	0.20	0.9
		25 mg	95	0.01	0.262	-0.8	-0.10	0.00	0.20	0.8
	Week 8	Placebo	100	-0.01	0.245	-0.8	-0.10	0.00	0.10	0.7
		12.5 mg	91	-0.01	0.266	-0.7	-0.20	0.00	0.20	0.8
		25 mg	94	0.00	0.288	-0.7	-0.10	0.00	0.20	0.8
	Week 12	Placebo	100	0.00	0.271	-0.9	-0.20	0.00	0.20	0.7
		12.5 mg	91	0.06	0.317	-0.6	-0.10	0.00	0.20	1.1
		25 mg	94	0.04	0.260	-0.6	-0.10	0.00	0.20	0.7
Creatinine (mg/dL)	Week 2	Placebo	100	-0.001	0.0495	-0.16	-0.030	0.000	0.030	0.12
		12.5 mg	92	0.014	0.0521	-0.12	-0.020	0.010	0.040	0.17
		25 mg	96	0.022	0.0595	-0.15	-0.015	0.015	0.060	0.16
	Week 4	Placebo	100	-0.000	0.0540	-0.12	-0.040	0.000	0.030	0.16
		12.5 mg	90	0.018	0.0513	-0.11	-0.020	0.020	0.060	0.14
		25 mg	95	0.024	0.0590	-0.13	-0.010	0.020	0.060	0.18
	Week 8	Placebo	100	-0.006	0.0474	-0.15	-0.030	0.000	0.020	0.11
		12.5 mg	91	0.019	0.0529	-0.09	-0.010	0.020	0.050	0.17
		25 mg	94	0.033	0.0581	-0.15	-0.010	0.030	0.070	0.22
	Week 12	Placebo	100	0.006	0.0532	-0.15	-0.020	0.010	0.040	0.14
		12.5 mg	91	0.022	0.0512	-0.11	-0.010	0.020	0.050	0.18
		25 mg	94	0.035	0.0689	-0.15	-0.010	0.025	0.070	0.32

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-33　血液生化学検査の評価時点別変化量（SYR-322/CCT-006 試験）（5/10）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
BUN (mg/dL)	Week 2	Placebo	100	-0.1	2.58	-9	-2.0	0.0	2.0	6
		12.5 mg	92	-0.0	2.96	-8	-2.0	0.0	2.0	8
		25 mg	96	-0.7	2.84	-8	-3.0	-1.0	1.0	6
	Week 4	Placebo	100	-0.4	2.82	-7	-2.0	0.0	1.0	8
		12.5 mg	90	-0.9	2.83	-8	-2.0	-1.0	1.0	6
		25 mg	95	-0.4	3.29	-8	-2.0	0.0	1.0	10
	Week 8	Placebo	100	-0.4	2.60	-6	-2.0	0.0	1.0	10
		12.5 mg	91	-0.4	2.46	-7	-2.0	-1.0	1.0	6
		25 mg	94	-0.4	2.80	-9	-2.0	-0.5	1.0	9
	Week 12	Placebo	100	-0.3	2.49	-8	-2.0	-0.5	1.0	8
		12.5 mg	91	-0.4	3.10	-10	-2.0	-1.0	2.0	5
		25 mg	94	-0.1	2.88	-8	-2.0	0.0	2.0	7
Uric Acid (mg/dL)	Week 2	Placebo	100	0.08	0.507	-1.3	-0.30	0.10	0.50	1.2
		12.5 mg	92	0.21	0.513	-1.1	-0.10	0.20	0.50	1.9
		25 mg	96	0.27	0.647	-1.2	-0.10	0.20	0.70	1.8
	Week 4	Placebo	100	-0.02	0.578	-1.5	-0.40	0.00	0.40	1.7
		12.5 mg	90	0.21	0.489	-1.0	-0.10	0.20	0.60	1.3
		25 mg	95	0.27	0.722	-1.2	-0.30	0.30	0.70	2.5
	Week 8	Placebo	100	-0.05	0.565	-1.6	-0.40	0.00	0.30	1.4
		12.5 mg	91	0.27	0.621	-2.3	-0.10	0.30	0.70	1.8
		25 mg	94	0.46	0.845	-1.5	-0.10	0.40	0.90	3.0
	Week 12	Placebo	100	0.02	0.629	-2.1	-0.30	-0.10	0.30	1.9
		12.5 mg	91	0.24	0.579	-1.9	-0.10	0.20	0.60	1.6
		25 mg	94	0.42	0.746	-2.5	0.00	0.30	0.80	2.2

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-33　血液生化学検査の評価時点別変化量（SYR-322/CCT-006 試験）（6/10）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
CPK/CK (IU/L)	Week 2	Placebo	100	5.9	56.61	-110	-15.5	0.5	19.0	409
		12.5 mg	92	0.7	28.38	-84	-13.0	0.5	14.0	99
		25 mg	96	17.5	204.53	-143	-19.0	-2.0	9.0	1974
	Week 4	Placebo	100	4.8	43.23	-95	-17.0	1.5	15.5	222
		12.5 mg	90	5.0	62.44	-115	-15.0	-1.0	15.0	502
		25 mg	95	-3.1	43.33	-131	-17.0	-3.0	13.0	176
	Week 8	Placebo	100	0.5	43.27	-127	-16.0	-4.5	19.0	197
		12.5 mg	91	-2.9	31.29	-93	-10.0	-2.0	10.0	122
		25 mg	94	10.7	63.71	-118	-11.0	4.0	20.0	339
	Week 12	Placebo	100	12.6	71.61	-136	-15.0	2.0	24.0	498
		12.5 mg	91	2.6	31.25	-86	-13.0	2.0	13.0	125
		25 mg	94	11.0	78.52	-118	-12.0	3.5	19.0	623
LDH (IU/L)	Week 2	Placebo	100	0.5	17.52	-41	-11.0	0.0	9.0	44
		12.5 mg	92	0.0	19.00	-52	-9.0	1.0	8.5	77
		25 mg	96	-1.3	17.26	-35	-12.5	-5.0	7.0	56
	Week 4	Placebo	100	0.1	17.29	-33	-11.0	0.5	11.0	78
		12.5 mg	90	0.7	20.36	-59	-10.0	1.0	15.0	64
		25 mg	95	-0.9	17.62	-48	-12.0	0.0	10.0	51
	Week 8	Placebo	100	-4.6	16.72	-43	-13.0	-3.0	5.0	45
		12.5 mg	91	-2.0	18.69	-62	-12.0	-3.0	10.0	39
		25 mg	94	1.9	19.03	-36	-11.0	2.0	10.0	106
	Week 12	Placebo	100	-0.0	17.63	-45	-10.0	-1.0	9.0	52
		12.5 mg	91	3.1	19.95	-44	-10.0	3.0	12.0	72
		25 mg	94	1.7	13.77	-25	-7.0	3.0	10.0	35

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-33　血液生化学検査の評価時点別変化量（SYR-322/CCT-006 試験）（7/10）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Potassium (mEq/L)	Week 2	Placebo	100	0.02	0.278	-0.6	-0.20	0.00	0.20	1.0
		12.5 mg	92	0.12	0.263	-0.7	-0.10	0.10	0.30	0.7
		25 mg	96	0.05	0.274	-0.6	-0.15	0.05	0.20	0.9
	Week 4	Placebo	100	0.03	0.283	-0.9	-0.10	0.00	0.20	0.8
		12.5 mg	90	0.08	0.267	-0.8	-0.10	0.10	0.20	0.8
		25 mg	95	0.06	0.270	-0.5	-0.10	0.10	0.20	1.2
	Week 8	Placebo	100	0.04	0.279	-1.0	-0.10	0.10	0.20	0.8
		12.5 mg	91	0.16	0.305	-0.5	0.00	0.10	0.30	1.1
		25 mg	94	0.04	0.289	-0.6	-0.10	0.00	0.20	1.1
	Week 12	Placebo	100	0.01	0.270	-0.8	-0.10	0.00	0.10	0.8
		12.5 mg	91	0.08	0.264	-0.5	-0.10	0.10	0.30	0.8
		25 mg	94	0.06	0.299	-0.5	-0.10	0.00	0.20	1.2
Sodium (mEq/L)	Week 2	Placebo	100	0.1	1.49	-3	-1.0	0.0	1.0	4
		12.5 mg	92	0.5	1.53	-4	-1.0	0.5	2.0	4
		25 mg	96	0.8	1.73	-5	0.0	1.0	2.0	5
	Week 4	Placebo	100	0.4	1.73	-4	-1.0	0.0	1.5	5
		12.5 mg	90	0.5	1.74	-5	0.0	1.0	1.0	4
		25 mg	95	1.1	1.82	-4	0.0	1.0	3.0	5
	Week 8	Placebo	100	0.6	1.68	-4	0.0	0.0	2.0	5
		12.5 mg	91	0.9	1.90	-4	0.0	1.0	2.0	6
		25 mg	94	0.9	1.59	-4	0.0	1.0	2.0	5
	Week 12	Placebo	100	0.4	1.79	-4	-1.0	1.0	1.5	5
		12.5 mg	91	0.6	1.70	-5	0.0	1.0	2.0	6
		25 mg	94	0.8	1.65	-3	0.0	0.0	2.0	4

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-33　血液生化学検査の評価時点別変化量（SYR-322/CCT-006 試験）（8/10）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Calcium (mg/dL)	Week 2	Placebo	100	0.01	0.288	-1.0	-0.20	0.00	0.20	0.9
		12.5 mg	92	0.01	0.298	-0.7	-0.20	0.00	0.20	0.7
		25 mg	96	-0.04	0.309	-1.0	-0.20	0.00	0.20	0.6
	Week 4	Placebo	100	-0.04	0.309	-0.7	-0.30	-0.05	0.20	0.7
		12.5 mg	90	-0.02	0.331	-0.7	-0.30	0.00	0.20	0.7
		25 mg	95	0.02	0.337	-1.0	-0.20	0.00	0.30	1.2
	Week 8	Placebo	100	-0.02	0.299	-0.8	-0.20	0.00	0.20	0.7
		12.5 mg	91	0.03	0.354	-0.8	-0.20	0.00	0.20	0.8
		25 mg	94	0.04	0.334	-0.8	-0.20	0.10	0.30	1.2
	Week 12	Placebo	100	-0.05	0.307	-0.9	-0.20	0.00	0.10	0.7
		12.5 mg	91	0.02	0.354	-0.8	-0.30	0.00	0.20	1.1
		25 mg	94	0.03	0.329	-0.8	-0.20	0.05	0.20	1.0
Chloride (mEq/L)	Week 2	Placebo	100	-0.1	1.78	-5	-1.0	0.0	1.0	6
		12.5 mg	92	0.8	1.71	-4	0.0	1.0	2.0	5
		25 mg	96	0.9	1.94	-3	0.0	1.0	2.0	6
	Week 4	Placebo	100	0.4	1.99	-3	-1.0	0.0	2.0	6
		12.5 mg	90	0.5	2.08	-5	-1.0	0.0	2.0	5
		25 mg	95	0.9	2.05	-4	-1.0	1.0	2.0	6
	Week 8	Placebo	100	1.0	1.70	-3	0.0	1.0	2.0	5
		12.5 mg	91	1.4	2.15	-4	0.0	1.0	3.0	7
		25 mg	94	1.1	2.14	-6	0.0	1.0	3.0	6
	Week 12	Placebo	100	0.5	2.01	-4	-1.0	1.0	2.0	7
		12.5 mg	91	0.8	1.95	-5	0.0	1.0	2.0	6
		25 mg	94	0.8	1.83	-4	-1.0	1.0	2.0	4

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表 2.7.4.7-付録-33　血液生化学検査の評価時点別変化量（SYR-322/CCT-006 試験）（9/10）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Inorganic Phosphorus (mg/dL)	Week 2	Placebo	100	0.04	0.343	-0.8	-0.20	0.00	0.30	1.2
		12.5 mg	92	-0.01	0.364	-0.8	-0.30	0.00	0.20	1.0
		25 mg	96	0.03	0.455	-1.4	-0.30	0.10	0.30	1.2
	Week 4	Placebo	100	0.03	0.409	-0.9	-0.30	0.00	0.30	1.3
		12.5 mg	90	0.07	0.332	-0.7	-0.10	0.10	0.30	1.0
		25 mg	95	0.10	0.453	-1.5	-0.10	0.10	0.30	1.6
	Week 8	Placebo	100	0.01	0.417	-1.1	-0.30	0.00	0.25	1.2
		12.5 mg	91	0.07	0.425	-0.8	-0.20	0.10	0.40	1.7
		25 mg	94	0.01	0.392	-1.0	-0.20	0.00	0.30	0.9
	Week 12	Placebo	100	0.03	0.366	-1.1	-0.20	0.10	0.30	0.8
		12.5 mg	91	-0.01	0.310	-0.6	-0.30	0.00	0.10	1.0
		25 mg	94	0.05	0.418	-0.9	-0.20	0.00	0.30	1.7
Lactic Acid (mg/dL)	Week 2	Placebo	100	-0.20	5.339	-18.1	-2.80	0.45	2.85	16.0
		12.5 mg	92	-0.66	4.457	-8.7	-3.80	-0.45	1.25	22.4
		25 mg	96	-0.65	4.274	-11.2	-2.90	-0.60	1.55	16.7
	Week 4	Placebo	100	-0.70	5.923	-23.2	-3.70	-0.30	2.35	15.3
		12.5 mg	90	-0.14	5.955	-14.7	-3.50	-0.30	2.20	24.4
		25 mg	95	-0.62	4.939	-12.9	-3.10	-0.80	2.30	15.8
	Week 8	Placebo	100	0.04	5.349	-19.9	-2.65	0.30	3.10	12.2
		12.5 mg	91	-1.10	3.902	-13.2	-3.30	-1.00	1.60	8.3
		25 mg	94	-0.34	4.018	-12.0	-2.40	-0.40	1.80	15.1
	Week 12	Placebo	100	0.64	6.099	-15.2	-3.15	0.20	3.05	20.6
		12.5 mg	91	-1.09	3.981	-19.0	-3.60	-0.30	1.50	5.6
		25 mg	94	-0.33	4.836	-8.3	-3.30	-0.90	1.40	23.6

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表 2.7.4.7-付録-33　血液生化学検査の評価時点別変化量（SYR-322/CCT-006 試験）（10/10）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Pyruvic Acid (mg/dL)	Week 2	Placebo	100	-0.005	0.2511	-0.89	-0.090	0.010	0.145	0.59
		12.5 mg	92	-0.044	0.2267	-0.70	-0.195	-0.035	0.115	0.66
		25 mg	96	-0.065	0.2430	-0.77	-0.190	-0.070	0.095	0.40
	Week 4	Placebo	100	-0.012	0.2969	-1.22	-0.155	0.015	0.145	1.07
		12.5 mg	90	-0.039	0.2291	-0.92	-0.190	-0.045	0.140	0.42
		25 mg	95	-0.052	0.2728	-1.05	-0.200	-0.040	0.110	0.59
	Week 8	Placebo	100	-0.005	0.2444	-0.64	-0.130	0.000	0.175	0.59
		12.5 mg	91	-0.030	0.2633	-0.73	-0.180	-0.030	0.130	0.81
		25 mg	94	-0.017	0.2328	-0.64	-0.170	-0.015	0.110	0.84
	Week 12	Placebo	100	0.031	0.3174	-0.90	-0.130	0.035	0.175	0.78
		12.5 mg	91	-0.014	0.2154	-0.52	-0.150	0.000	0.110	0.61
		25 mg	94	-0.020	0.2458	-0.83	-0.160	0.005	0.110	0.74
Creatinine Clearance (mL/min)	Week 2	Placebo	100	-0.042	11.2248	-34.46	-5.294	-0.091	5.185	42.06
		12.5 mg	92	-2.838	11.6144	-36.38	-8.412	-2.451	3.274	28.10
		25 mg	96	-4.078	12.0539	-48.52	-11.640	-2.740	3.145	27.47
	Week 4	Placebo	100	0.153	11.5353	-30.49	-5.588	0.225	6.814	39.48
		12.5 mg	90	-2.729	11.5186	-36.01	-10.106	-2.981	4.360	47.84
		25 mg	95	-4.448	12.0392	-46.74	-10.391	-1.390	2.281	21.27
	Week 8	Placebo	100	0.597	10.1480	-30.33	-5.470	-0.127	5.571	29.15
		12.5 mg	91	-3.426	13.6088	-67.86	-11.089	-1.773	3.686	50.46
		25 mg	94	-6.023	12.2853	-51.44	-12.338	-4.541	1.196	26.82
	Week 12	Placebo	100	-1.480	10.9625	-25.49	-7.963	-2.067	3.208	41.99
		12.5 mg	91	-3.628	11.9368	-69.19	-9.268	-1.934	2.718	21.66
		25 mg	94	-6.416	12.7106	-43.55	-12.943	-5.579	1.998	31.06

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表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（1/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
ALT	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	71	3	74	-	80	-	80	-	78	2	80
		Upper	-	4	22	26	-	3	9	12	-	4	12	16
		Total	-	75	25	100	-	83	9	92	-	82	14	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	69	5	74	-	77	-	77	-	76	2	78
		Upper	-	6	20	26	-	4	9	13	-	5	12	17
		Total	-	75	25	100	-	81	9	90	-	81	14	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	70	5	75	-	77	1	78	-	78	6	84
		Upper	-	5	20	25	-	5	8	13	-	2	8	10
		Total	-	75	25	100	-	82	9	91	-	80	14	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	69	8	77	-	78	-	78	-	78	4	82
		Upper	-	6	17	23	-	4	9	13	-	2	10	12
		Total	-	75	25	100	-	82	9	91	-	80	14	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（2/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
AST	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	79	2	81	-	81	1	82	-	85	2	87
		Upper	-	3	16	19	-	4	6	10	-	4	5	9
		Total	-	82	18	100	-	85	7	92	-	89	7	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	79	3	82	-	82	-	82	-	85	2	87
		Upper	-	3	15	18	-	1	7	8	-	3	5	8
		Total	-	82	18	100	-	83	7	90	-	88	7	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	78	3	81	-	83	1	84	-	83	1	84
		Upper	-	4	15	19	-	1	6	7	-	4	6	10
		Total	-	82	18	100	-	84	7	91	-	87	7	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	80	8	88	-	82	2	84	-	82	3	85
		Upper	-	2	10	12	-	2	5	7	-	5	4	9
		Total	-	82	18	100	-	84	7	91	-	87	7	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（3/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
GGT	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	68	-	68	-	69	6	75	-	75	3	78
		Upper	-	4	28	32	-	3	14	17	-	1	17	18
		Total	-	72	28	100	-	72	20	92	-	76	20	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	69	-	69	-	67	4	71	-	73	2	75
		Upper	-	3	28	31	-	3	16	19	-	2	18	20
		Total	-	72	28	100	-	70	20	90	-	75	20	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	70	1	71	-	67	4	71	-	73	5	78
		Upper	-	2	27	29	-	4	16	20	-	2	14	16
		Total	-	72	28	100	-	71	20	91	-	75	19	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	70	4	74	-	68	4	72	-	75	4	79
		Upper	-	2	24	26	-	3	16	19	-	-	15	15
		Total	-	72	28	100	-	71	20	91	-	75	19	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（4/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Alkaline Phosphatase	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	86	5	91	-	74	7	81	-	81	6	87
		Upper	-	2	7	9	-	1	10	11	-	1	8	9
		Total	-	88	12	100	-	75	17	92	-	82	14	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	86	5	91	-	71	7	78	-	81	5	86
		Upper	-	2	7	9	-	2	10	12	-	1	8	9
		Total	-	88	12	100	-	73	17	90	-	82	13	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	87	5	92	-	71	10	81	-	79	7	86
		Upper	-	1	7	8	-	3	7	10	-	2	6	8
		Total	-	88	12	100	-	74	17	91	-	81	13	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	83	7	90	-	73	7	80	-	81	6	87
		Upper	-	5	5	10	-	1	10	11	-	-	7	7
		Total	-	88	12	100	-	74	17	91	-	81	13	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（5/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Bilirubin Total	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	94	1	95	-	85	4	89	-	86	7	93
		Upper	-	1	4	5	-	2	1	3	-	1	2	3
		Total	-	95	5	100	-	87	5	92	-	87	9	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	93	1	94	-	82	3	85	-	82	7	89
		Upper	-	2	4	6	-	3	2	5	-	4	2	6
		Total	-	95	5	100	-	85	5	90	-	86	9	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	94	1	95	-	86	4	90	-	79	4	83
		Upper	-	1	4	5	-	-	1	1	-	6	5	11
		Total	-	95	5	100	-	86	5	91	-	85	9	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	94	2	96	-	84	3	87	-	83	5	88
		Upper	-	1	3	4	-	2	2	4	-	2	4	6
		Total	-	95	5	100	-	86	5	91	-	85	9	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（6/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Protein Total	Week 2	Lower	1	3	-	4	-	2	-	2	1	5	-	6
		Normal	2	87	4	93	3	84	1	88	-	85	3	88
		Upper	-	2	1	3	-	1	1	2	-	1	1	2
		Total	3	92	5	100	3	87	2	92	1	91	4	96
	Week 4	Lower	1	3	-	4	-	1	-	1	-	3	-	3
		Normal	2	87	2	91	3	79	1	83	1	86	4	91
		Upper	-	2	3	5	-	5	1	6	-	1	-	1
		Total	3	92	5	100	3	85	2	90	1	90	4	95
	Week 8	Lower	2	6	-	8	2	3	-	5	1	3	-	4
		Normal	1	85	3	89	1	81	1	83	-	83	4	87
		Upper	-	1	2	3	-	2	1	3	-	3	-	3
		Total	3	92	5	100	3	86	2	91	1	89	4	94
	Week 12	Lower	1	5	-	6	-	2	-	2	1	2	-	3
		Normal	2	84	5	91	3	77	1	81	-	85	4	89
		Upper	-	3	-	3	-	7	1	8	-	2	-	2
		Total	3	92	5	100	3	86	2	91	1	89	4	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（7/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Albumin	Week 2	Lower	-	-	-	-	-	-	-	-	-	1	-	1
		Normal	-	100	-	100	-	92	-	92	-	95	-	95
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	-	100	-	100	-	92	-	92	-	96	-	96
	Week 4	Lower	-	1	-	1	-	-	-	-	-	-	-	-
		Normal	-	99	-	99	-	90	-	90	-	95	-	95
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	-	100	-	100	-	90	-	90	-	95	-	95
	Week 8	Lower	-	1	-	1	-	-	-	-	-	-	-	-
		Normal	-	99	-	99	-	90	-	90	-	94	-	94
		Upper	-	-	-	-	-	1	-	1	-	-	-	-
		Total	-	100	-	100	-	91	-	91	-	94	-	94
	Week 12	Lower	-	1	-	1	-	-	-	-	-	-	-	-
		Normal	-	99	-	99	-	89	-	89	-	94	-	94
		Upper	-	-	-	-	-	2	-	2	-	-	-	-
		Total	-	100	-	100	-	91	-	91	-	94	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（8/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Creatinine	Week 2	Lower	15	3	-	18	11	2	-	13	10	4	-	14
		Normal	7	74	-	81	3	74	1	78	13	61	-	74
		Upper	-	-	1	1	-	-	1	1	-	1	7	8
		Total	22	77	1	100	14	76	2	92	23	66	7	96
	Week 4	Lower	18	7	-	25	11	5	-	16	12	3	-	15
		Normal	4	70	1	75	3	68	-	71	10	63	1	74
		Upper	-	-	-	-	-	1	2	3	-	-	6	6
		Total	22	77	1	100	14	74	2	90	22	66	7	95
	Week 8	Lower	19	7	-	26	9	3	-	12	9	4	-	13
		Normal	3	69	1	73	5	71	-	76	13	61	-	74
		Upper	-	1	-	1	-	1	2	3	-	-	7	7
		Total	22	77	1	100	14	75	2	91	22	65	7	94
	Week 12	Lower	16	5	-	21	9	2	-	11	9	2	-	11
		Normal	6	71	-	77	5	72	-	77	13	63	2	78
		Upper	-	1	1	2	-	1	2	3	-	-	5	5
		Total	22	77	1	100	14	75	2	91	22	65	7	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（9/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
BUN	Week 2	Lower	1	-	-	1	-	-	-	-	-	-	-	-
		Normal	-	99	-	99	1	89	1	91	-	95	1	96
		Upper	-	-	-	-	-	-	1	1	-	-	-	-
		Total	1	99	-	100	1	89	2	92	-	95	1	96
	Week 4	Lower	-	-	-	-	1	1	-	2	-	2	-	2
		Normal	1	98	-	99	-	85	1	86	-	90	1	91
		Upper	-	1	-	1	-	1	1	2	-	2	-	2
		Total	1	99	-	100	1	87	2	90	-	94	1	95
	Week 8	Lower	1	-	-	1	1	1	-	2	-	1	-	1
		Normal	-	98	-	98	-	86	1	87	-	92	-	92
		Upper	-	1	-	1	-	1	1	2	-	1	-	1
		Total	1	99	-	100	1	88	2	91	-	94	-	94
	Week 12	Lower	1	1	-	2	-	1	-	1	-	1	-	1
		Normal	-	97	-	97	1	85	1	87	-	93	-	93
		Upper	-	1	-	1	-	2	1	3	-	-	-	-
		Total	1	99	-	100	1	88	2	91	-	94	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（10/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Uric Acid	Week 2	Lower	3	3	-	6	3	1	-	4	3	-	-	3
		Normal	1	82	2	85	6	72	2	80	3	82	3	88
		Upper	-	4	5	9	-	5	3	8	-	2	3	5
		Total	4	89	7	100	9	78	5	92	6	84	6	96
	Week 4	Lower	3	4	-	7	4	-	-	4	4	-	-	4
		Normal	1	82	2	85	5	72	1	78	2	80	1	83
		Upper	-	3	5	8	-	4	4	8	-	3	5	8
		Total	4	89	7	100	9	76	5	90	6	83	6	95
	Week 8	Lower	3	5	-	8	2	-	-	2	3	-	-	3
		Normal	1	81	2	84	7	72	1	80	3	77	2	82
		Upper	-	3	5	8	-	5	4	9	-	5	4	9
		Total	4	89	7	100	9	77	5	91	6	82	6	94
	Week 12	Lower	3	3	-	6	3	-	-	3	3	-	-	3
		Normal	1	82	2	85	6	76	1	83	3	76	1	80
		Upper	-	4	5	9	-	1	4	5	-	6	5	11
		Total	4	89	7	100	9	77	5	91	6	82	6	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（11/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
CPK/CK	Week 2	Lower	4	2	-	6	2	1	-	3	11	5	-	16
		Normal	5	81	5	91	3	81	2	86	1	75	-	76
		Upper	-	2	1	3	-	2	1	3	-	1	3	4
		Total	9	85	6	100	5	84	3	92	12	81	3	96
	Week 4	Lower	4	2	-	6	3	2	-	5	7	6	-	13
		Normal	5	78	4	87	2	77	2	81	5	73	-	78
		Upper	-	5	2	7	-	3	1	4	-	1	3	4
		Total	9	85	6	100	5	82	3	90	12	80	3	95
	Week 8	Lower	5	4	-	9	5	3	-	8	8	3	-	11
		Normal	4	79	5	88	-	78	3	81	4	72	-	76
		Upper	-	2	1	3	-	2	-	2	-	4	3	7
		Total	9	85	6	100	5	83	3	91	12	79	3	94
	Week 12	Lower	5	4	-	9	4	2	-	6	5	2	-	7
		Normal	4	77	4	85	1	78	2	81	6	76	-	82
		Upper	-	4	2	6	-	3	1	4	1	1	3	5
		Total	9	85	6	100	5	83	3	91	12	79	3	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（12/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
LDH	Week 2	Lower	-	3	-	3	-	-	-	-	2	1	-	3
		Normal	2	92	-	94	2	86	1	89	1	88	1	90
		Upper	-	2	1	3	-	3	-	3	-	2	1	3
		Total	2	97	1	100	2	89	1	92	3	91	2	96
	Week 4	Lower	1	1	-	2	1	-	-	1	2	-	-	2
		Normal	1	94	1	96	1	86	1	88	1	90	1	92
		Upper	-	2	-	2	-	1	-	1	-	1	-	1
		Total	2	97	1	100	2	87	1	90	3	91	1	95
	Week 8	Lower	1	1	-	2	-	2	-	2	2	-	-	2
		Normal	1	96	1	98	2	86	1	89	1	88	-	89
		Upper	-	-	-	-	-	-	-	-	-	2	1	3
		Total	2	97	1	100	2	88	1	91	3	90	1	94
	Week 12	Lower	1	1	-	2	-	1	-	1	2	-	-	2
		Normal	1	95	-	96	2	85	1	88	1	88	-	89
		Upper	-	1	1	2	-	2	-	2	-	2	1	3
		Total	2	97	1	100	2	88	1	91	3	90	1	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（13/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Potassium	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	100	-	100	-	88	-	88	1	91	-	92
		Upper	-	-	-	-	-	3	1	4	-	3	1	4
		Total	-	100	-	100	-	91	1	92	1	94	1	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	100	-	100	-	86	-	86	1	90	-	91
		Upper	-	-	-	-	-	3	1	4	-	3	1	4
		Total	-	100	-	100	-	89	1	90	1	93	1	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	99	-	99	-	86	1	87	1	88	1	90
		Upper	-	1	-	1	-	4	-	4	-	4	-	4
		Total	-	100	-	100	-	90	1	91	1	92	1	94
	Week 12	Lower	-	2	-	2	-	-	-	-	-	-	-	-
		Normal	-	96	-	96	-	87	1	88	1	88	-	89
		Upper	-	2	-	2	-	3	-	3	-	4	1	5
		Total	-	100	-	100	-	90	1	91	1	92	1	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（14/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Sodium	Week 2	Lower	8	6	-	14	4	2	-	6	4	-	-	4
		Normal	3	83	-	86	2	84	-	86	9	83	-	92
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	11	89	-	100	6	86	-	92	13	83	-	96
	Week 4	Lower	4	5	-	9	4	3	-	7	3	1	-	4
		Normal	7	84	-	91	2	81	-	83	10	81	-	91
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	11	89	-	100	6	84	-	90	13	82	-	95
	Week 8	Lower	3	3	-	6	3	1	-	4	4	2	-	6
		Normal	8	86	-	94	3	84	-	87	9	79	-	88
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	11	89	-	100	6	85	-	91	13	81	-	94
	Week 12	Lower	5	7	-	12	3	2	-	5	-	-	-	-
		Normal	6	82	-	88	3	83	-	86	13	81	-	94
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	11	89	-	100	6	85	-	91	13	81	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（15/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Calcium	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	99	1	100	-	91	-	91	-	96	-	96
		Upper	-	-	-	-	-	-	1	1	-	-	-	-
		Total	-	99	1	100	-	91	1	92	-	96	-	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	99	1	100	-	89	-	89	-	95	-	95
		Upper	-	-	-	-	-	-	1	1	-	-	-	-
		Total	-	99	1	100	-	89	1	90	-	95	-	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	99	-	99	-	90	1	91	-	94	-	94
		Upper	-	-	1	1	-	-	-	-	-	-	-	-
		Total	-	99	1	100	-	90	1	91	-	94	-	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	99	1	100	-	90	1	91	-	93	-	93
		Upper	-	-	-	-	-	-	-	-	-	1	-	1
		Total	-	99	1	100	-	90	1	91	-	94	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（16/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Chloride	Week 2	Lower	4	4	-	8	3	1	-	4	2	1	-	3
		Normal	6	86	-	92	-	88	-	88	1	91	-	92
		Upper	-	-	-	-	-	-	-	-	-	1	-	1
		Total	10	90	-	100	3	89	-	92	3	93	-	96
	Week 4	Lower	3	5	-	8	3	3	-	6	1	1	-	2
		Normal	7	85	-	92	-	84	-	84	2	91	-	93
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	10	90	-	100	3	87	-	90	3	92	-	95
	Week 8	Lower	1	1	-	2	2	2	-	4	1	5	-	6
		Normal	9	89	-	98	1	86	-	87	2	86	-	88
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	10	90	-	100	3	88	-	91	3	91	-	94
	Week 12	Lower	6	4	-	10	1	1	-	2	2	-	-	2
		Normal	4	85	-	89	2	87	-	89	1	91	-	92
		Upper	-	1	-	1	-	-	-	-	-	-	-	-
		Total	10	90	-	100	3	88	-	91	3	91	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（17/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Inorganic Phosphorus	Week 2	Lower	-	-	-	-	1	1	-	2	1	1	-	2
		Normal	1	99	-	100	-	90	-	90	-	94	-	94
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	1	99	-	100	1	91	-	92	1	95	-	96
	Week 4	Lower	-	-	-	-	1	1	-	2	1	1	-	2
		Normal	1	98	-	99	-	87	-	87	-	92	-	92
		Upper	-	1	-	1	-	1	-	1	-	1	-	1
		Total	1	99	-	100	1	89	-	90	1	94	-	95
	Week 8	Lower	-	-	-	-	1	1	-	2	1	-	-	1
		Normal	1	98	-	99	-	87	-	87	-	91	-	91
		Upper	-	1	-	1	-	2	-	2	-	2	-	2
		Total	1	99	-	100	1	90	-	91	1	93	-	94
	Week 12	Lower	-	-	-	-	-	-	-	-	1	1	-	2
		Normal	1	99	-	100	1	90	-	91	-	91	-	91
		Upper	-	-	-	-	-	-	-	-	-	1	-	1
		Total	1	99	-	100	1	90	-	91	1	93	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（18/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Lactic Acid	Week 2	Lower	1	1	-	2	-	1	-	1	-	2	-	2
		Normal	1	69	11	81	2	71	9	82	-	79	8	87
		Upper	-	10	7	17	-	3	6	9	-	4	3	7
		Total	2	80	18	100	2	75	15	92	-	85	11	96
	Week 4	Lower	2	-	-	2	-	1	-	1	-	3	-	3
		Normal	-	69	15	84	2	66	8	76	-	74	9	83
		Upper	-	11	3	14	-	6	7	13	-	7	2	9
		Total	2	80	18	100	2	73	15	90	-	84	11	95
	Week 8	Lower	1	1	-	2	1	3	-	4	-	2	-	2
		Normal	1	66	9	76	1	70	8	79	-	74	7	81
		Upper	-	13	9	22	-	1	7	8	-	8	3	11
		Total	2	80	18	100	2	74	15	91	-	84	10	94
	Week 12	Lower	1	-	-	1	1	1	-	2	-	-	-	-
		Normal	1	66	10	77	1	73	11	85	-	78	4	82
		Upper	-	14	8	22	-	-	4	4	-	6	6	12
		Total	2	80	18	100	2	74	15	91	-	84	10	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-34　血液生化学検査の正異判定のクロス表（SYR-322/CCT-006 試験）（19/19）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Pyruvic Acid	Week 2	Lower	5	3	1	9	2	7	1	10	3	8	1	12
		Normal	7	60	10	77	3	63	6	72	6	59	12	77
		Upper	-	6	8	14	-	7	3	10	-	5	2	7
		Total	12	69	19	100	5	77	10	92	9	72	15	96
	Week 4	Lower	3	1	-	4	3	9	-	12	1	5	1	7
		Normal	9	60	13	82	1	63	8	72	7	60	11	78
		Upper	-	8	6	14	-	4	2	6	-	7	3	10
		Total	12	69	19	100	4	76	10	90	8	72	15	95
	Week 8	Lower	6	3	-	9	1	6	1	8	5	2	-	7
		Normal	6	61	14	81	3	66	4	73	2	65	7	74
		Upper	-	5	5	10	-	5	5	10	1	4	8	13
		Total	12	69	19	100	4	77	10	91	8	71	15	94
	Week 12	Lower	3	1	1	5	2	5	-	7	5	2	-	7
		Normal	8	56	11	75	2	66	6	74	3	62	8	73
		Upper	1	12	7	20	-	6	4	10	-	7	7	14
		Total	12	69	19	100	4	77	10	91	8	71	15	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-35　尿検査の評価時点別変化量（SYR-322/CCT-006 試験）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Specific Gravity	Week 2	Placebo	100	-0.0008	0.00601	-0.019	-0.0050	0.0000	0.0025	0.016
		12.5 mg	92	0.0001	0.00616	-0.020	-0.0050	0.0005	0.0050	0.016
		25 mg	96	-0.0017	0.00697	-0.019	-0.0050	-0.0010	0.0020	0.017
	Week 4	Placebo	100	-0.0006	0.00553	-0.016	-0.0050	0.0000	0.0030	0.012
		12.5 mg	90	-0.0014	0.00642	-0.018	-0.0050	0.0000	0.0020	0.012
		25 mg	95	-0.0017	0.00644	-0.020	-0.0050	0.0000	0.0010	0.015
	Week 8	Placebo	100	-0.0005	0.00604	-0.015	-0.0050	-0.0010	0.0040	0.017
		12.5 mg	91	-0.0006	0.00646	-0.015	-0.0050	-0.0010	0.0030	0.017
		25 mg	94	-0.0022	0.00724	-0.020	-0.0050	-0.0010	0.0020	0.020
	Week 12	Placebo	100	-0.0008	0.00661	-0.020	-0.0050	0.0000	0.0040	0.013
		12.5 mg	91	-0.0010	0.00582	-0.018	-0.0040	0.0000	0.0020	0.013
		25 mg	94	-0.0020	0.00706	-0.025	-0.0050	-0.0020	0.0010	0.015

総括報告書（5.3.5.1-2）表 14.4.11

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（1/20）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Specific Gravity	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	100	-	100	-	92	-	92	-	96	-	96
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	-	100	-	100	-	92	-	92	-	96	-	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	100	-	100	-	90	-	90	-	95	-	95
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	-	100	-	100	-	90	-	90	-	95	-	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	100	-	100	-	91	-	91	-	94	-	94
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	-	100	-	100	-	91	-	91	-	94	-	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	100	-	100	-	91	-	91	-	94	-	94
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	-	100	-	100	-	91	-	91	-	94	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（2/20）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
pH	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	100	-	100	-	92	-	92	-	96	-	96
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	-	100	-	100	-	92	-	92	-	96	-	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	100	-	100	-	90	-	90	-	95	-	95
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	-	100	-	100	-	90	-	90	-	95	-	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	100	-	100	-	91	-	91	-	94	-	94
		Upper	-	-	-	-	-	-	-	-	-	-	-	-
		Total	-	100	-	100	-	91	-	91	-	94	-	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	100	-	100	-	90	-	90	-	94	-	94
		Upper	-	-	-	-	-	1	-	1	-	-	-	-
		Total	-	100	-	100	-	91	-	91	-	94	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（3/20）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Urinary Glucose	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	56	5	61	-	60	16	76	-	57	20	77
		Upper	-	8	31	39	-	1	15	16	-	-	19	19
		Total	-	64	36	100	-	61	31	92	-	57	39	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	55	6	61	-	59	17	76	-	53	23	76
		Upper	-	9	30	39	-	1	13	14	-	3	16	19
		Total	-	64	36	100	-	60	30	90	-	56	39	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	54	8	62	-	58	18	76	-	54	20	74
		Upper	-	10	28	38	-	2	13	15	-	2	18	20
		Total	-	64	36	100	-	60	31	91	-	56	38	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	50	7	57	-	60	17	77	-	54	20	74
		Upper	-	14	29	43	-	-	14	14	-	2	18	20
		Total	-	64	36	100	-	60	31	91	-	56	38	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（4/20）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Urinary Protein	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	59	12	71	-	56	7	63	-	62	15	77
		Upper	-	6	23	29	-	8	21	29	-	4	15	19
		Total	-	65	35	100	-	64	28	92	-	66	30	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	59	8	67	-	60	7	67	-	59	13	72
		Upper	-	6	27	33	-	2	21	23	-	6	17	23
		Total	-	65	35	100	-	62	28	90	-	65	30	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	57	12	69	-	57	8	65	-	57	16	73
		Upper	-	8	23	31	-	6	20	26	-	7	14	21
		Total	-	65	35	100	-	63	28	91	-	64	30	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	59	7	66	-	56	6	62	-	58	15	73
		Upper	-	6	28	34	-	7	22	29	-	6	15	21
		Total	-	65	35	100	-	63	28	91	-	64	30	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（5/20）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Urinary Ketones	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	88	4	92	-	79	3	82	-	83	10	93
		Upper	-	6	2	8	-	6	4	10	-	3	-	3
		Total	-	94	6	100	-	85	7	92	-	86	10	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	87	3	90	-	74	5	79	-	84	8	92
		Upper	-	7	3	10	-	9	2	11	-	1	2	3
		Total	-	94	6	100	-	83	7	90	-	85	10	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	85	4	89	-	76	4	80	-	82	7	89
		Upper	-	9	2	11	-	8	3	11	-	2	3	5
		Total	-	94	6	100	-	84	7	91	-	84	10	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	88	4	92	-	79	5	84	-	81	10	91
		Upper	-	6	2	8	-	5	2	7	-	3	-	3
		Total	-	94	6	100	-	84	7	91	-	84	10	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（6/20）

			Placebo				12.5 mg				25 mg			
			Week 0				Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Urinary Occult Blood	Week 2	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	84	6	90	-	83	3	86	-	83	5	88
		Upper	-	5	5	10	-	4	2	6	-	5	3	8
		Total	-	89	11	100	-	87	5	92	-	88	8	96
	Week 4	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	87	3	90	-	81	1	82	-	82	3	85
		Upper	-	2	8	10	-	4	4	8	-	5	5	10
		Total	-	89	11	100	-	85	5	90	-	87	8	95
	Week 8	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	85	4	89	-	84	3	87	-	84	7	91
		Upper	-	4	7	11	-	2	2	4	-	2	1	3
		Total	-	89	11	100	-	86	5	91	-	86	8	94
	Week 12	Lower	-	-	-	-	-	-	-	-	-	-	-	-
		Normal	-	88	5	93	-	83	3	86	-	79	6	85
		Upper	-	1	6	7	-	3	2	5	-	7	2	9
		Total	-	89	11	100	-	86	5	91	-	86	8	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（7/20）

pH

Frequency				Week 0		
				Min - 8.0	8.1 - Max	Total
Treatment	Placebo	Week 2	Min - 8.0	100	-	100
			8.1 - Max	-	-	-
			Total	100	-	100
		Week 4	Min - 8.0	100	-	100
			8.1 - Max	-	-	-
			Total	100	-	100
		Week 8	Min - 8.0	100	-	100
			8.1 - Max	-	-	-
			Total	100	-	100
		Week 12	Min - 8.0	100	-	100
			8.1 - Max	-	-	-
			Total	100	-	100
	12.5 mg	Week 2	Min - 8.0	92	-	92
			8.1 - Max	-	-	-
			Total	92	-	92
		Week 4	Min - 8.0	90	-	90
			8.1 - Max	-	-	-
			Total	90	-	90
		Week 8	Min - 8.0	91	-	91
			8.1 - Max	-	-	-
			Total	91	-	91
		Week 12	Min - 8.0	90	-	90
			8.1 - Max	1	-	1
			Total	91	-	91

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（8/20）

pH

Frequency				Week 0		
				Min - 8.0	8.1 - Max	Total
Treatment	25 mg	Week 2	Min - 8.0	96	-	96
			8.1 - Max	-	-	-
			Total	96	-	96
		Week 4	Min - 8.0	95	-	95
			8.1 - Max	-	-	-
			Total	95	-	95
		Week 8	Min - 8.0	94	-	94
			8.1 - Max	-	-	-
			Total	94	-	94
		Week 12	Min - 8.0	94	-	94
			8.1 - Max	-	-	-
			Total	94	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（9/20）

Urinary Glucose

Frequency				Week 0						
				-	+	2+	3+	4+	5+	Total
Treatment	Placebo	Week 2	-	56	1	2	2	-	-	61
			+	6	2	3	1	-	2	14
			2+	2	2	-	2	-	1	7
			3+	-	2	-	-	1	4	7
			4+	-	-	-	-	-	2	2
			5+	-	1	2	2	2	2	9
			Total	64	8	7	7	3	11	100
		Week 4	-	55	2	3	-	-	1	61
			+	6	2	1	2	-	1	12
			2+	2	3	1	1	1	4	12
			3+	-	-	-	1	-	1	2
			4+	-	-	-	-	-	1	1
			5+	1	1	2	3	2	3	12
			Total	64	8	7	7	3	11	100
		Week 8	-	54	3	4	1	-	-	62
			+	7	3	-	1	-	1	12
			2+	2	-	2	1	1	3	9
			3+	1	2	1	-	1	4	9
			4+	-	-	-	2	-	-	2
			5+	-	-	-	2	1	3	6
			Total	64	8	7	7	3	11	100
		Week 12	-	50	1	2	2	-	2	57
			+	8	3	1	1	-	1	14
			2+	3	3	1	3	-	3	13
			3+	2	1	1	1	1	-	6
			4+	1	-	-	-	1	1	3
			5+	-	-	2	-	1	4	7
			Total	64	8	7	7	3	11	100

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（10/20）

Urinary Glucose

Frequency				Week 0						
				-	+	2+	3+	4+	5+	Total
Treatment	12.5 mg	Week 2	-	60	11	2	1	-	2	76
			+	1	1	1	-	2	1	6
			2+	-	2	1	-	-	2	5
			3+	-	1	-	-	1	2	4
			4+	-	-	-	-	-	1	1
			5+	-	-	-	-	-	-	-
			Total	61	15	4	1	3	8	92
		Week 4	-	59	12	2	1	1	1	76
			+	1	-	1	-	1	2	5
			2+	-	1	-	-	-	3	4
			3+	-	1	1	-	1	-	3
			4+	-	-	-	-	-	-	-
			5+	-	1	-	-	-	1	2
			Total	60	15	4	1	3	7	90
		Week 8	-	58	11	1	1	1	4	76
			+	1	1	3	-	1	2	8
			2+	1	2	-	-	1	1	5
			3+	-	1	-	-	-	-	1
			4+	-	-	-	-	-	-	-
			5+	-	-	-	-	-	1	1
			Total	60	15	4	1	3	8	91
		Week 12	-	60	12	2	1	1	1	77
			+	-	1	1	-	1	4	7
			2+	-	1	-	-	-	2	3
			3+	-	-	1	-	1	-	2
			4+	-	-	-	-	-	1	1
			5+	-	1	-	-	-	-	1
			Total	60	15	4	1	3	8	91

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（11/20）

Urinary Glucose

Frequency				Week 0						
				-	+	2+	3+	4+	5+	Total
Treatment	25 mg	Week 2	-	57	3	8	6	-	3	77
			+	-	5	1	1	-	1	8
			2+	-	-	1	2	1	3	7
			3+	-	1	-	1	-	-	2
			4+	-	1	-	-	-	-	1
			5+	-	-	-	-	-	1	1
			Total	57	10	10	10	1	8	96
		Week 4	-	53	8	6	6	-	3	76
			+	3	2	2	2	-	1	10
			2+	-	-	-	-	-	2	2
			3+	-	-	-	-	1	-	1
			4+	-	-	1	1	-	-	2
			5+	-	-	1	1	-	2	4
			Total	56	10	10	10	1	8	95
		Week 8	-	54	6	6	6	-	2	74
			+	2	2	1	2	-	2	9
			2+	-	-	2	1	-	2	5
			3+	-	1	1	1	1	-	4
			4+	-	-	-	-	-	-	-
			5+	-	-	-	-	-	2	2
			Total	56	9	10	10	1	8	94
		Week 12	-	54	7	6	4	-	3	74
			+	-	1	2	1	-	2	6
			2+	1	-	2	3	-	1	7
			3+	-	1	-	2	-	1	4
			4+	1	-	-	-	-	-	1
			5+	-	-	-	-	1	1	2
			Total	56	9	10	10	1	8	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（12/20）

Urinary Protein

Frequency				Week 0						
				-	+-	+	2+	3+	4+	Total
Treatment	Placebo	Week 2	-	59	6	6	-	-	-	71
			+-	4	6	1	-	-	-	11
			+	2	4	4	2	-	-	12
			2+	-	-	1	4	-	-	5
			3+	-	-	-	1	-	-	1
			4+	-	-	-	-	-	-	-
			Total	65	16	12	7	-	-	100
		Week 4	-	59	6	2	-	-	-	67
			+-	4	4	2	-	-	-	10
			+	2	5	5	2	-	-	14
			2+	-	1	1	4	-	-	6
			3+	-	-	2	1	-	-	3
			4+	-	-	-	-	-	-	-
			Total	65	16	12	7	-	-	100
		Week 8	-	57	7	5	-	-	-	69
			+-	7	5	-	-	-	-	12
			+	1	3	3	2	-	-	9
			2+	-	1	4	4	-	-	9
			3+	-	-	-	1	-	-	1
			4+	-	-	-	-	-	-	-
			Total	65	16	12	7	-	-	100
		Week 12	-	59	6	1	-	-	-	66
			+-	5	5	2	-	-	-	12
			+	1	4	7	4	-	-	16
			2+	-	1	2	2	-	-	5
			3+	-	-	-	1	-	-	1
			4+	-	-	-	-	-	-	-
			Total	65	16	12	7	-	-	100

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（13/20）

Urinary Protein

Frequency				Week 0						
				-	+-	+	2+	3+	4+	Total
Treatment	12.5 mg	Week 2	-	56	7	-	-	-	-	63
			+-	6	2	2	2	-	-	12
			+	2	2	6	-	-	-	10
			2+	-	1	-	3	1	-	5
			3+	-	-	-	1	1	-	2
			4+	-	-	-	-	-	-	-
			Total	64	12	8	6	2	-	92
		Week 4	-	60	6	-	1	-	-	67
			+-	1	3	2	1	-	-	7
			+	1	3	6	1	-	-	11
			2+	-	-	-	3	2	-	5
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	62	12	8	6	2	-	90
		Week 8	-	57	6	1	1	-	-	65
			+-	5	1	-	1	-	-	7
			+	1	4	7	1	1	-	14
			2+	-	1	-	3	-	-	4
			3+	-	-	-	-	1	-	1
			4+	-	-	-	-	-	-	-
			Total	63	12	8	6	2	-	91
		Week 12	-	56	5	-	1	-	-	62
			+-	6	5	4	-	-	-	15
			+	1	2	4	2	1	-	10
			2+	-	-	-	3	1	-	4
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	63	12	8	6	2	-	91

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（14/20）

Urinary Protein

Frequency				Week 0						
				-	+-	+	2+	3+	4+	Total
Treatment	25 mg	Week 2	-	62	9	5	1	-	-	77
			+-	4	4	2	1	-	-	11
			+	-	-	3	-	-	-	3
			2+	-	-	1	3	1	-	5
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	66	13	11	5	1	-	96
		Week 4	-	59	10	3	-	-	-	72
			+-	3	1	4	1	-	-	9
			+	2	2	4	1	-	-	9
			2+	1	-	-	3	1	-	5
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	65	13	11	5	1	-	95
		Week 8	-	57	9	6	1	-	-	73
			+-	6	2	3	-	-	-	11
			+	1	2	2	-	-	-	5
			2+	-	-	-	4	1	-	5
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	64	13	11	5	1	-	94
		Week 12	-	58	10	3	2	-	-	73
			+-	3	2	4	-	-	-	9
			+	3	1	4	1	-	-	9
			2+	-	-	-	2	1	-	3
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	64	13	11	5	1	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（15/20）

Urinary Ketones

Frequency				Week 0						
				-	+-	+	2+	3+	4+	Total
Treatment	Placebo	Week 2	-	88	3	-	1	-	-	92
			+-	5	2	-	-	-	-	7
			+	1	-	-	-	-	-	1
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	94	5	-	1	-	-	100
		Week 4	-	87	2	-	1	-	-	90
			+-	7	3	-	-	-	-	10
			+	-	-	-	-	-	-	-
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	94	5	-	1	-	-	100
		Week 8	-	85	3	-	1	-	-	89
			+-	9	2	-	-	-	-	11
			+	-	-	-	-	-	-	-
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	94	5	-	1	-	-	100
		Week 12	-	88	3	-	1	-	-	92
			+-	6	2	-	-	-	-	8
			+	-	-	-	-	-	-	-
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	94	5	-	1	-	-	100

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（16/20）

Urinary Ketones

Frequency				Week 0						
				-	+-	+	2+	3+	4+	Total
Treatment	12.5 mg	Week 2	-	79	3	-	-	-	-	82
			+-	5	3	1	-	-	-	9
			+	1	-	-	-	-	-	1
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	85	6	1	-	-	-	92
		Week 4	-	74	5	-	-	-	-	79
			+-	9	1	-	-	-	-	10
			+	-	-	1	-	-	-	1
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	83	6	1	-	-	-	90
		Week 8	-	76	4	-	-	-	-	80
			+-	8	1	-	-	-	-	9
			+	-	1	1	-	-	-	2
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	84	6	1	-	-	-	91
		Week 12	-	79	5	-	-	-	-	84
			+-	3	1	1	-	-	-	5
			+	2	-	-	-	-	-	2
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	84	6	1	-	-	-	91

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（17/20）

Urinary Ketones

Frequency				Week 0						
				-	+-	+	2+	3+	4+	Total
Treatment	25 mg	Week 2	-	83	9	-	1	-	-	93
			+-	2	-	-	-	-	-	2
			+	-	-	-	-	-	-	-
			2+	1	-	-	-	-	-	1
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	86	9	-	1	-	-	96
		Week 4	-	84	7	-	1	-	-	92
			+-	1	2	-	-	-	-	3
			+	-	-	-	-	-	-	-
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	85	9	-	1	-	-	95
		Week 8	-	82	6	-	1	-	-	89
			+-	2	1	-	-	-	-	3
			+	-	2	-	-	-	-	2
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	-	-	-	-	-	-	-
			Total	84	9	-	1	-	-	94
		Week 12	-	81	9	-	1	-	-	91
			+-	2	-	-	-	-	-	2
			+	-	-	-	-	-	-	-
			2+	-	-	-	-	-	-	-
			3+	-	-	-	-	-	-	-
			4+	1	-	-	-	-	-	1
			Total	84	9	-	1	-	-	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（18/20）

Urinary Occult Blood

Frequency				Week 0					
				-	+-	+	2+	3+	Total
Treatment	Placebo	Week 2	-	84	2	3	-	1	90
			+-	3	-	1	-	-	4
			+	1	2	-	1	-	4
			2+	-	-	-	-	-	-
			3+	1	-	-	-	1	2
			Total	89	4	4	1	2	100
		Week 4	-	87	1	2	-	-	90
			+-	2	1	-	-	-	3
			+	-	1	2	1	1	5
			2+	-	1	-	-	1	2
			3+	-	-	-	-	-	-
			Total	89	4	4	1	2	100
		Week 8	-	85	2	1	-	1	89
			+-	3	-	1	-	-	4
			+	-	2	-	1	1	4
			2+	1	-	2	-	-	3
			3+	-	-	-	-	-	-
			Total	89	4	4	1	2	100
		Week 12	-	88	2	2	-	1	93
			+-	1	-	1	-	-	2
			+	-	2	1	1	-	4
			2+	-	-	-	-	-	-
			3+	-	-	-	-	1	1
			Total	89	4	4	1	2	100

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（19/20）

Urinary Occult Blood

Frequency				Week 0					
				-	+-	+	2+	3+	Total
Treatment	12.5 mg	Week 2	-	83	-	2	-	1	86
			+-	1	-	-	-	-	1
			+	-	-	1	-	-	1
			2+	-	-	-	1	-	1
			3+	3	-	-	-	-	3
			Total	87	-	3	1	1	92
		Week 4	-	81	-	1	-	-	82
			+-	3	-	1	-	-	4
			+	-	-	-	-	-	-
			2+	-	-	-	-	-	-
			3+	1	-	1	1	1	4
			Total	85	-	3	1	1	90
		Week 8	-	84	-	2	-	1	87
			+-	2	-	1	-	-	3
			+	-	-	-	-	-	-
			2+	-	-	-	1	-	1
			3+	-	-	-	-	-	-
			Total	86	-	3	1	1	91
		Week 12	-	83	-	3	-	-	86
			+-	1	-	-	1	-	2
			+	1	-	-	-	-	1
			2+	-	-	-	-	-	-
			3+	1	-	-	-	1	2
			Total	86	-	3	1	1	91

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-36　尿検査の正異判定のクロス表（SYR-322/CCT-006 試験）（20/20）

Urinary Occult Blood

Frequency				Week 0					
				-	+-	+	2+	3+	Total
Treatment	25 mg	Week 2	-	83	1	1	-	3	88
			+-	5	2	-	-	-	7
			+	-	-	1	-	-	1
			2+	-	-	-	-	-	-
			3+	-	-	-	-	-	-
			Total	88	3	2	-	3	96
		Week 4	-	82	-	1	-	2	85
			+-	3	2	-	-	-	5
			+	1	-	1	-	-	2
			2+	-	1	-	-	-	1
			3+	1	-	-	-	1	2
			Total	87	3	2	-	3	95
		Week 8	-	84	2	2	-	3	91
			+-	1	-	-	-	-	1
			+	-	1	-	-	-	1
			2+	-	-	-	-	-	-
			3+	1	-	-	-	-	1
			Total	86	3	2	-	3	94
		Week 12	-	79	1	2	-	3	85
			+-	3	1	-	-	-	4
			+	3	1	-	-	-	4
			2+	1	-	-	-	-	1
			3+	-	-	-	-	-	-
			Total	86	3	2	-	3	94

総括報告書（5.3.5.1-2）表 14.4.12

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（1/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
RBC ($x10^4/\mu L$)	Week 2	12.5 mg	97	-6.1	19.03	-61	-20.0	-9.0	10.0	44
		25 mg	102	-9.9	18.08	-67	-21.0	-8.0	1.0	31
	Week 4	12.5 mg	135	-3.7	20.19	-77	-16.0	-4.0	8.0	46
		25 mg	138	-6.5	18.95	-63	-18.0	-6.5	4.0	48
	Week 8	12.5 mg	141	-3.6	21.89	-47	-18.0	-5.0	9.0	78
		25 mg	143	-4.4	18.39	-81	-15.0	-5.0	8.0	49
	Week 12	12.5 mg	140	-1.9	23.06	-70	-17.0	-1.0	11.0	78
		25 mg	141	-1.6	20.60	-62	-14.0	-1.0	11.0	57
	Week 16	12.5 mg	138	-6.3	20.19	-51	-19.0	-8.0	9.0	52
		25 mg	135	-5.0	20.92	-58	-16.0	-8.0	9.0	55
	Week 20	12.5 mg	135	-5.2	21.07	-58	-19.0	-6.0	10.0	45
		25 mg	134	-5.9	22.42	-71	-19.0	-7.0	8.0	50
	Week 24	12.5 mg	134	-1.5	21.02	-57	-16.0	-4.0	12.0	69
		25 mg	134	-5.0	20.87	-83	-17.0	-1.5	7.0	84
	Week 28	12.5 mg	135	-6.6	22.28	-79	-22.0	-6.0	8.0	57
		25 mg	132	-8.7	22.13	-68	-22.5	-8.0	4.5	98
	Week 32	12.5 mg	135	-5.5	23.35	-99	-21.0	-3.0	9.0	60
		25 mg	129	-9.0	21.87	-80	-22.0	-8.0	3.0	80
	Week 36	12.5 mg	133	-5.2	23.00	-100	-19.0	-1.0	9.0	71
		25 mg	129	-5.4	22.42	-63	-17.0	-7.0	10.0	63
	Week 40	12.5 mg	132	-4.2	23.20	-109	-18.0	-2.5	9.0	81
		25 mg	129	-5.1	19.92	-51	-19.0	-6.0	7.0	64
	Week 44	12.5 mg	81	-1.2	22.61	-50	-19.0	-1.0	9.0	62
		25 mg	83	-4.3	23.93	-74	-20.0	-6.0	9.0	64
	Week 48	12.5 mg	81	-2.4	20.69	-63	-16.0	-5.0	12.0	52
		25 mg	83	-3.3	22.06	-88	-13.0	-4.0	11.0	68
	Week 52	12.5 mg	81	-0.5	21.59	-61	-14.0	2.0	10.0	57
		25 mg	83	-2.8	22.33	-67	-19.0	0.0	13.0	56

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（2/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
WBC (/μL)	Week 2	12.5 mg	97	-53.6	1333.55	-4500	-700.0	0.0	500.0	4500
		25 mg	102	162.7	1230.14	-5400	-400.0	100.0	600.0	5400
	Week 4	12.5 mg	135	-14.8	1382.38	-5700	-600.0	0.0	600.0	5100
		25 mg	138	221.7	1271.23	-5400	-500.0	200.0	800.0	5100
	Week 8	12.5 mg	141	100.0	1200.30	-3700	-600.0	100.0	700.0	6600
		25 mg	143	349.7	1459.74	-4300	-300.0	300.0	1100.0	5900
	Week 12	12.5 mg	140	233.6	1320.98	-5700	-600.0	200.0	950.0	4700
		25 mg	141	190.1	1608.87	-5100	-600.0	100.0	800.0	11600
	Week 16	12.5 mg	138	197.8	1221.25	-3800	-500.0	300.0	900.0	4000
		25 mg	135	264.4	1202.95	-5200	-400.0	200.0	900.0	3300
	Week 20	12.5 mg	135	265.2	1414.71	-4400	-400.0	200.0	900.0	6700
		25 mg	134	391.0	1288.85	-4200	-400.0	300.0	800.0	5600
	Week 24	12.5 mg	134	220.9	1373.27	-3500	-500.0	100.0	900.0	7800
		25 mg	134	189.6	1302.24	-4900	-400.0	100.0	700.0	7400
	Week 28	12.5 mg	135	283.0	1276.28	-3600	-400.0	300.0	1100.0	4500
		25 mg	132	372.7	1335.72	-3300	-400.0	300.0	950.0	6800
	Week 32	12.5 mg	135	317.0	1468.45	-4100	-400.0	400.0	900.0	7300
		25 mg	129	387.6	1260.08	-5600	-200.0	400.0	1000.0	5100
	Week 36	12.5 mg	133	201.5	1243.59	-3500	-400.0	200.0	800.0	6300
		25 mg	129	305.4	1320.88	-5300	-300.0	200.0	900.0	6400
	Week 40	12.5 mg	132	136.4	1327.99	-4700	-450.0	200.0	800.0	4500
		25 mg	129	292.2	1526.77	-5300	-300.0	200.0	900.0	8700
	Week 44	12.5 mg	81	151.9	1385.92	-3400	-400.0	200.0	800.0	5500
		25 mg	83	289.2	1295.40	-5800	-300.0	200.0	1100.0	3000
	Week 48	12.5 mg	81	229.6	1264.46	-3900	-400.0	100.0	900.0	3700
		25 mg	83	169.9	1265.66	-4900	-400.0	100.0	800.0	4200
	Week 52	12.5 mg	81	135.8	1270.27	-4100	-600.0	0.0	800.0	4200
		25 mg	83	-2.4	1086.72	-4500	-600.0	-100.0	700.0	2400

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（3/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Hemoglobin (g/dL)	Week 2	12.5 mg	97	-0.17	0.595	-1.8	-0.60	-0.20	0.30	1.2
		25 mg	102	-0.29	0.586	-2.3	-0.70	-0.30	0.00	1.1
	Week 4	12.5 mg	135	-0.17	0.628	-2.3	-0.50	-0.20	0.20	1.4
		25 mg	138	-0.26	0.584	-2.3	-0.60	-0.30	0.10	1.6
	Week 8	12.5 mg	141	-0.24	0.685	-1.8	-0.70	-0.30	0.20	2.2
		25 mg	143	-0.27	0.567	-2.2	-0.60	-0.30	0.10	1.4
	Week 12	12.5 mg	140	-0.23	0.693	-2.1	-0.70	-0.30	0.30	1.8
		25 mg	141	-0.23	0.652	-2.2	-0.70	-0.20	0.30	1.4
	Week 16	12.5 mg	138	-0.39	0.621	-1.7	-0.80	-0.40	0.00	1.6
		25 mg	135	-0.36	0.658	-2.5	-0.70	-0.40	0.00	1.0
	Week 20	12.5 mg	135	-0.38	0.633	-1.7	-0.80	-0.50	0.10	1.6
		25 mg	134	-0.39	0.670	-3.0	-0.80	-0.40	0.00	1.1
	Week 24	12.5 mg	134	-0.25	0.647	-1.9	-0.70	-0.30	0.20	1.9
		25 mg	134	-0.34	0.653	-3.8	-0.70	-0.30	0.00	0.9
	Week 28	12.5 mg	135	-0.36	0.718	-2.8	-0.80	-0.40	0.20	1.4
		25 mg	132	-0.40	0.658	-3.5	-0.80	-0.30	0.00	1.3
	Week 32	12.5 mg	135	-0.27	0.750	-3.2	-0.90	-0.20	0.20	1.5
		25 mg	129	-0.35	0.695	-3.8	-0.80	-0.30	0.00	1.5
	Week 36	12.5 mg	133	-0.14	0.711	-2.9	-0.70	-0.10	0.30	1.9
		25 mg	129	-0.13	0.686	-3.3	-0.50	-0.10	0.30	1.5
	Week 40	12.5 mg	132	-0.09	0.726	-3.4	-0.60	-0.10	0.40	2.0
		25 mg	129	-0.08	0.645	-2.1	-0.50	-0.10	0.30	1.9
	Week 44	12.5 mg	81	0.02	0.712	-1.8	-0.40	0.00	0.40	1.9
		25 mg	83	-0.03	0.749	-2.7	-0.40	-0.10	0.50	1.8
	Week 48	12.5 mg	81	0.04	0.631	-1.9	-0.40	0.00	0.40	1.6
		25 mg	83	0.10	0.721	-3.1	-0.20	0.10	0.50	2.3
	Week 52	12.5 mg	81	0.12	0.692	-2.1	-0.40	0.10	0.50	1.9
		25 mg	83	0.12	0.757	-2.7	-0.30	0.20	0.50	2.0

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（4/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Hematocrit (%)	Week 2	12.5 mg	97	-0.62	1.894	-5.1	-1.90	-0.80	0.80	4.5
		25 mg	102	-0.97	1.785	-6.7	-2.00	-0.70	0.20	3.2
	Week 4	12.5 mg	135	-0.45	1.932	-7.1	-1.70	-0.50	0.70	3.8
		25 mg	138	-0.77	1.821	-6.0	-1.90	-0.55	0.20	4.1
	Week 8	12.5 mg	141	-0.55	2.076	-5.3	-1.70	-0.80	0.60	9.1
		25 mg	143	-0.66	1.749	-7.2	-1.70	-0.60	0.40	4.9
	Week 12	12.5 mg	140	-0.50	2.109	-6.6	-2.00	-0.35	0.60	5.9
		25 mg	141	-0.48	1.870	-5.8	-1.70	-0.60	0.80	4.5
	Week 16	12.5 mg	138	-0.92	1.895	-5.3	-2.30	-1.00	0.50	3.8
		25 mg	135	-0.84	1.974	-7.3	-2.00	-1.00	0.80	3.5
	Week 20	12.5 mg	135	-0.78	1.958	-5.6	-2.20	-0.70	0.70	3.1
		25 mg	134	-0.82	2.131	-8.3	-2.00	-0.95	0.70	3.7
	Week 24	12.5 mg	134	-0.27	1.981	-4.7	-1.70	-0.30	1.10	4.7
		25 mg	134	-0.62	1.958	-9.9	-1.70	-0.45	0.60	5.1
	Week 28	12.5 mg	135	-0.75	2.175	-7.4	-2.30	-0.70	0.50	4.2
		25 mg	132	-0.86	2.048	-9.2	-2.10	-0.70	0.40	4.5
	Week 32	12.5 mg	135	-0.57	2.313	-8.9	-2.20	-0.60	0.90	5.5
		25 mg	129	-0.83	2.027	-10.2	-2.10	-0.90	0.40	5.3
	Week 36	12.5 mg	133	-0.29	2.191	-8.8	-1.70	0.00	1.10	5.5
		25 mg	129	-0.16	1.974	-8.5	-1.30	-0.20	1.00	6.1
	Week 40	12.5 mg	132	-0.07	2.275	-9.3	-1.55	-0.20	1.35	6.5
		25 mg	129	-0.10	1.800	-4.6	-1.10	0.10	1.00	5.5
	Week 44	12.5 mg	81	0.11	2.170	-5.1	-1.20	0.10	1.30	7.0
		25 mg	83	-0.08	2.196	-6.3	-1.50	-0.20	1.20	5.9
	Week 48	12.5 mg	81	0.03	2.014	-5.4	-1.30	-0.20	1.50	4.3
		25 mg	83	0.04	2.091	-8.2	-0.80	0.00	1.10	5.8
	Week 52	12.5 mg	81	0.24	2.091	-6.0	-1.10	0.40	1.50	5.5
		25 mg	83	0.12	2.151	-6.6	-1.30	0.30	1.60	5.4

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（5/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Platelet Count ($x10^4/\mu L$)	Week 2	12.5 mg	94	0.03	3.060	-12.4	-1.50	-0.20	1.20	12.5
		25 mg	101	0.63	2.854	-5.8	-1.10	0.60	2.10	8.8
	Week 4	12.5 mg	133	-0.12	2.766	-8.6	-1.70	-0.30	1.50	8.9
		25 mg	137	-0.02	2.689	-9.0	-1.50	0.00	1.40	9.8
	Week 8	12.5 mg	139	-0.19	3.085	-11.3	-2.10	0.10	1.40	10.0
		25 mg	142	-0.13	2.789	-6.2	-1.80	-0.30	1.20	17.5
	Week 12	12.5 mg	137	-0.36	2.962	-13.7	-2.10	-0.30	1.20	6.4
		25 mg	139	-0.34	2.696	-9.8	-1.70	-0.30	1.30	7.0
	Week 16	12.5 mg	135	-0.56	2.642	-11.0	-1.70	-0.60	1.10	6.1
		25 mg	134	-0.24	3.004	-9.8	-2.20	-0.15	1.50	11.2
	Week 20	12.5 mg	133	-0.62	3.173	-14.2	-2.40	-0.50	1.30	6.3
		25 mg	133	-0.24	3.078	-9.8	-2.00	-0.40	1.40	12.4
	Week 24	12.5 mg	131	-1.01	3.194	-14.6	-2.80	-0.70	0.80	9.7
		25 mg	133	-1.02	3.987	-11.0	-2.90	-1.10	0.60	26.6
	Week 28	12.5 mg	133	-1.47	3.160	-15.8	-2.90	-1.40	0.30	9.8
		25 mg	131	-1.03	2.900	-11.3	-2.50	-0.80	0.80	8.2
	Week 32	12.5 mg	132	-1.68	3.359	-14.8	-3.05	-1.50	0.00	7.3
		25 mg	128	-1.72	2.889	-11.4	-3.20	-1.75	0.10	7.2
	Week 36	12.5 mg	131	-2.35	3.277	-17.2	-4.20	-2.00	-0.80	8.1
		25 mg	128	-2.28	2.708	-10.3	-3.45	-2.00	-0.55	6.6
	Week 40	12.5 mg	130	-2.17	3.151	-16.0	-3.80	-2.05	-0.70	8.7
		25 mg	128	-2.39	2.858	-13.8	-3.80	-2.30	-0.80	5.6
	Week 44	12.5 mg	80	-2.49	3.033	-17.2	-3.65	-2.45	-0.75	3.9
		25 mg	82	-1.67	2.318	-8.1	-3.20	-1.60	-0.30	6.3
	Week 48	12.5 mg	79	-2.13	3.205	-16.3	-3.70	-2.00	-0.50	7.5
		25 mg	82	-1.48	2.807	-9.5	-3.00	-1.60	0.10	6.6
	Week 52	12.5 mg	80	-1.87	4.003	-19.8	-3.90	-2.10	0.25	10.1
		25 mg	82	-1.89	2.297	-7.0	-2.90	-2.00	-0.70	6.2

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（6/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Neutrophils (%)	Week 2	12.5 mg	97	2.07	7.262	-21.3	-1.50	2.10	5.80	26.2
		25 mg	102	1.20	5.714	-11.8	-2.70	1.70	5.10	16.0
	Week 4	12.5 mg	135	1.71	8.870	-22.2	-2.70	1.60	6.40	32.0
		25 mg	138	0.66	6.685	-15.8	-3.80	0.45	5.00	15.9
	Week 8	12.5 mg	141	1.77	6.959	-16.8	-1.90	1.90	6.60	21.1
		25 mg	143	1.34	6.654	-15.5	-3.30	0.50	5.40	23.0
	Week 12	12.5 mg	140	1.82	7.554	-20.1	-2.20	2.65	6.25	24.8
		25 mg	141	0.94	6.729	-19.7	-2.70	0.90	4.80	20.9
	Week 16	12.5 mg	138	1.08	7.380	-20.3	-2.70	1.55	6.10	24.4
		25 mg	135	0.47	6.782	-18.5	-3.40	0.30	5.70	19.1
	Week 20	12.5 mg	135	1.57	7.808	-24.1	-2.50	1.00	5.90	29.9
		25 mg	134	1.52	7.025	-15.4	-3.50	1.60	5.40	27.7
	Week 24	12.5 mg	134	2.36	8.591	-22.7	-2.00	2.65	7.00	33.4
		25 mg	134	0.75	6.885	-14.7	-4.60	0.50	5.60	21.2
	Week 28	12.5 mg	135	2.41	8.206	-33.0	-2.30	2.50	6.70	21.5
		25 mg	132	0.65	6.325	-14.3	-3.70	1.00	4.75	22.7
	Week 32	12.5 mg	135	2.00	8.305	-24.1	-2.80	1.80	5.90	27.8
		25 mg	129	0.64	6.312	-11.6	-3.90	0.10	5.00	18.3
	Week 36	12.5 mg	133	2.43	6.991	-16.2	-2.30	2.70	7.00	19.7
		25 mg	129	1.05	6.229	-17.4	-2.40	0.90	5.10	24.3
	Week 40	12.5 mg	132	2.09	7.752	-18.9	-2.70	2.10	6.40	27.5
		25 mg	129	1.32	5.891	-14.4	-1.90	0.90	5.00	17.1
	Week 44	12.5 mg	81	2.04	8.513	-18.2	-3.10	0.10	6.80	27.6
		25 mg	83	1.42	5.791	-11.0	-2.60	1.10	5.30	19.9
	Week 48	12.5 mg	81	2.87	7.872	-11.3	-3.10	3.00	7.70	31.8
		25 mg	83	2.04	6.359	-12.4	-2.50	2.70	5.20	20.4
	Week 52	12.5 mg	81	2.53	7.659	-20.3	-1.50	2.50	7.00	24.8
		25 mg	83	1.24	5.466	-13.0	-2.40	0.60	5.30	17.7

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（7/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Eosinophils (%)	Week 2	12.5 mg	97	-0.28	1.640	-4.7	-0.90	-0.20	0.30	6.5
		25 mg	102	-0.02	1.187	-3.7	-0.60	-0.15	0.40	5.5
	Week 4	12.5 mg	135	-0.05	1.722	-7.4	-1.00	-0.10	0.60	7.1
		25 mg	138	0.21	1.416	-5.6	-0.40	0.00	0.70	7.0
	Week 8	12.5 mg	141	-0.13	1.714	-7.7	-1.00	-0.30	0.50	5.2
		25 mg	143	0.18	1.654	-5.6	-0.60	0.00	0.80	8.9
	Week 12	12.5 mg	140	-0.17	1.730	-6.4	-0.95	-0.30	0.30	8.9
		25 mg	141	0.29	1.541	-5.1	-0.40	0.10	0.80	9.2
	Week 16	12.5 mg	138	-0.22	1.810	-7.2	-1.10	-0.30	0.50	6.0
		25 mg	135	0.24	1.485	-4.1	-0.50	0.00	0.90	7.5
	Week 20	12.5 mg	135	-0.41	1.858	-8.3	-1.40	-0.30	0.40	6.0
		25 mg	134	0.04	1.709	-6.5	-0.70	-0.10	0.70	8.0
	Week 24	12.5 mg	134	-0.48	1.967	-10.4	-1.30	-0.45	0.50	4.9
		25 mg	134	0.07	1.506	-5.1	-0.60	0.00	0.80	8.2
	Week 28	12.5 mg	135	-0.48	1.809	-5.3	-1.20	-0.50	0.40	5.4
		25 mg	132	-0.09	1.526	-4.0	-0.80	-0.20	0.45	9.3
	Week 32	12.5 mg	135	-0.47	1.774	-8.0	-1.20	-0.40	0.40	4.9
		25 mg	129	0.10	1.632	-5.0	-0.70	0.00	0.50	8.6
	Week 36	12.5 mg	133	-0.51	1.903	-9.3	-1.00	-0.40	0.50	4.0
		25 mg	129	0.05	1.830	-8.1	-0.80	-0.10	0.60	8.4
	Week 40	12.5 mg	132	-0.34	2.611	-8.3	-1.15	-0.30	0.40	21.1
		25 mg	129	0.03	1.984	-4.0	-0.80	-0.20	0.70	14.3
	Week 44	12.5 mg	81	-0.33	1.941	-8.0	-1.40	-0.40	0.50	6.2
		25 mg	83	0.06	1.651	-3.0	-0.70	-0.20	0.50	9.1
	Week 48	12.5 mg	81	-0.44	1.967	-9.5	-1.20	-0.30	0.50	5.5
		25 mg	83	0.07	1.505	-3.2	-0.70	-0.10	0.60	8.2
	Week 52	12.5 mg	81	-0.16	2.368	-9.5	-1.00	-0.10	0.90	9.3
		25 mg	83	0.29	1.685	-2.2	-0.40	0.00	0.50	9.3

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（8/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Monocytes (%)	Week 2	12.5 mg	97	0.41	1.411	-2.9	-0.60	0.30	1.10	4.7
		25 mg	102	0.18	1.529	-3.0	-0.80	-0.10	1.00	6.5
	Week 4	12.5 mg	135	0.18	1.481	-8.7	-0.40	0.30	1.10	3.5
		25 mg	138	0.53	1.740	-4.0	-0.50	0.40	1.40	10.5
	Week 8	12.5 mg	141	0.13	1.616	-10.5	-0.70	0.30	1.00	3.7
		25 mg	143	0.33	1.471	-4.0	-0.50	0.30	1.00	6.0
	Week 12	12.5 mg	140	0.15	1.482	-7.8	-0.60	0.20	1.00	3.9
		25 mg	141	0.41	1.455	-4.0	-0.30	0.50	1.10	3.9
	Week 16	12.5 mg	138	0.26	1.513	-8.3	-0.50	0.45	1.10	4.8
		25 mg	135	0.35	1.462	-3.9	-0.70	0.50	1.30	4.0
	Week 20	12.5 mg	135	0.22	1.670	-9.0	-0.90	0.30	1.30	4.6
		25 mg	134	0.32	1.547	-3.9	-0.70	0.30	1.40	5.4
	Week 24	12.5 mg	134	-0.12	1.694	-8.7	-0.90	-0.20	0.80	7.0
		25 mg	134	0.32	1.556	-4.0	-0.70	0.30	1.50	4.4
	Week 28	12.5 mg	135	0.03	1.663	-10.9	-0.80	0.20	1.00	4.7
		25 mg	132	0.20	1.564	-4.6	-0.60	0.40	1.25	4.7
	Week 32	12.5 mg	135	0.21	1.763	-9.3	-0.60	0.30	1.00	10.1
		25 mg	129	0.35	1.384	-5.0	-0.40	0.50	1.20	4.3
	Week 36	12.5 mg	133	0.05	1.558	-9.0	-0.90	0.00	1.30	3.2
		25 mg	129	0.11	1.661	-5.5	-0.90	0.20	1.10	4.5
	Week 40	12.5 mg	132	0.09	1.785	-9.7	-0.85	0.25	1.20	4.5
		25 mg	129	0.19	1.467	-3.7	-0.80	0.30	1.00	6.5
	Week 44	12.5 mg	81	0.10	1.486	-3.2	-0.90	0.30	0.90	4.1
		25 mg	83	0.03	1.484	-3.8	-1.00	0.10	1.00	3.1
	Week 48	12.5 mg	81	0.26	1.473	-3.9	-0.70	0.20	1.10	6.7
		25 mg	83	-0.07	1.413	-4.0	-0.90	0.10	0.60	3.2
	Week 52	12.5 mg	81	0.21	1.411	-2.8	-0.70	0.20	1.20	4.3
		25 mg	83	0.22	1.431	-4.0	-0.70	0.30	1.20	3.8

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（9/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Lymphocytes (%)	Week 2	12.5 mg	97	-2.17	6.535	-24.5	-5.20	-2.00	0.90	19.0
		25 mg	102	-1.42	4.940	-14.2	-4.70	-1.55	1.80	10.4
	Week 4	12.5 mg	135	-1.80	8.169	-28.3	-6.90	-1.70	2.70	19.9
		25 mg	138	-1.35	5.830	-17.0	-5.40	-0.75	2.20	15.7
	Week 8	12.5 mg	141	-1.65	6.120	-20.2	-5.40	-1.90	1.30	15.0
		25 mg	143	-1.76	5.722	-20.8	-5.40	-1.50	2.50	11.2
	Week 12	12.5 mg	140	-1.75	6.723	-24.2	-5.35	-2.35	1.70	19.2
		25 mg	141	-1.57	5.809	-21.6	-5.00	-1.50	1.70	18.3
	Week 16	12.5 mg	138	-1.01	6.486	-22.3	-5.70	-1.10	2.00	18.8
		25 mg	135	-0.93	6.297	-19.1	-5.30	-0.30	3.00	17.9
	Week 20	12.5 mg	135	-1.28	6.841	-27.2	-4.60	-1.20	2.50	23.1
		25 mg	134	-1.82	6.196	-21.2	-5.00	-1.30	2.10	15.3
	Week 24	12.5 mg	134	-1.66	7.311	-22.0	-5.20	-1.80	2.10	19.2
		25 mg	134	-1.03	6.074	-20.6	-4.80	-1.25	3.30	14.9
	Week 28	12.5 mg	135	-1.87	7.165	-21.0	-5.70	-1.30	2.10	26.4
		25 mg	132	-0.71	5.475	-19.9	-3.95	-0.50	2.30	12.6
	Week 32	12.5 mg	135	-1.68	7.435	-26.5	-5.70	-1.50	2.80	22.3
		25 mg	129	-0.99	5.592	-17.4	-4.70	-1.30	3.00	12.5
	Week 36	12.5 mg	133	-1.85	6.068	-18.7	-5.60	-2.50	1.80	15.1
		25 mg	129	-1.17	5.511	-21.6	-4.40	-2.00	1.60	18.2
	Week 40	12.5 mg	132	-1.74	6.664	-23.8	-5.80	-1.75	2.00	17.7
		25 mg	129	-1.42	5.310	-15.1	-4.80	-0.90	2.00	10.9
	Week 44	12.5 mg	81	-1.70	7.538	-24.3	-6.20	-0.20	2.70	14.5
		25 mg	83	-1.48	5.104	-17.4	-4.70	-1.70	1.90	11.6
	Week 48	12.5 mg	81	-2.66	7.024	-30.9	-6.10	-2.10	2.00	10.1
		25 mg	83	-2.03	5.433	-16.6	-5.30	-2.70	2.00	9.5
	Week 52	12.5 mg	81	-2.53	6.757	-23.9	-6.10	-2.00	0.80	18.7
		25 mg	83	-1.73	4.980	-16.1	-5.30	-1.70	1.40	9.0

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（10/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
Basophils (%)	Week 2	12.5 mg	97	-0.04	0.531	-2.4	-0.20	0.00	0.20	1.2
		25 mg	102	0.07	0.572	-2.7	-0.20	0.10	0.30	2.3
	Week 4	12.5 mg	135	-0.03	0.524	-1.8	-0.30	0.00	0.20	2.1
		25 mg	138	-0.05	0.527	-2.3	-0.20	-0.10	0.10	2.0
	Week 8	12.5 mg	141	-0.11	0.453	-2.0	-0.30	-0.10	0.10	1.1
		25 mg	143	-0.08	0.504	-2.3	-0.30	-0.10	0.20	1.0
	Week 12	12.5 mg	140	-0.06	0.531	-1.9	-0.25	0.00	0.20	2.3
		25 mg	141	-0.06	0.519	-2.1	-0.20	0.00	0.20	1.8
	Week 16	12.5 mg	138	-0.12	0.507	-2.0	-0.30	-0.10	0.10	1.6
		25 mg	135	-0.13	0.465	-2.0	-0.30	-0.10	0.10	1.0
	Week 20	12.5 mg	135	-0.10	0.477	-2.1	-0.30	-0.10	0.20	1.0
		25 mg	134	-0.06	0.592	-2.5	-0.30	0.00	0.20	1.5
	Week 24	12.5 mg	134	-0.09	0.466	-2.1	-0.30	0.00	0.20	0.9
		25 mg	134	-0.10	0.533	-2.1	-0.30	-0.10	0.10	1.8
	Week 28	12.5 mg	135	-0.09	0.502	-1.9	-0.30	0.00	0.20	1.4
		25 mg	132	-0.05	0.529	-2.3	-0.20	0.00	0.20	2.0
	Week 32	12.5 mg	135	-0.06	0.468	-1.6	-0.30	0.00	0.20	1.2
		25 mg	129	-0.10	0.525	-2.5	-0.30	0.00	0.20	1.5
	Week 36	12.5 mg	133	-0.12	0.471	-2.0	-0.30	-0.10	0.10	1.2
		25 mg	129	-0.04	0.571	-2.4	-0.40	0.00	0.20	1.5
	Week 40	12.5 mg	132	-0.09	0.453	-1.9	-0.20	0.00	0.10	1.0
		25 mg	129	-0.13	0.488	-2.4	-0.40	-0.10	0.10	1.1
	Week 44	12.5 mg	81	-0.12	0.464	-2.1	-0.20	-0.10	0.10	1.0
		25 mg	83	-0.02	0.520	-2.3	-0.30	0.00	0.20	2.2
	Week 48	12.5 mg	81	-0.04	0.525	-2.0	-0.20	-0.10	0.30	0.9
		25 mg	83	-0.01	0.542	-2.4	-0.20	0.00	0.30	1.0
	Week 52	12.5 mg	81	-0.06	0.532	-2.0	-0.30	0.00	0.20	1.0
		25 mg	83	-0.01	0.472	-2.2	-0.30	0.00	0.20	1.1

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（11/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
MCV (fL)	Week 2	12.5 mg	97	-0.2	1.04	-3	-1.0	0.0	0.0	3
		25 mg	102	-0.1	1.04	-3	-1.0	0.0	1.0	2
	Week 4	12.5 mg	135	-0.3	1.29	-4	-1.0	0.0	0.0	3
		25 mg	138	-0.4	1.31	-4	-1.0	0.0	0.0	4
	Week 8	12.5 mg	141	-0.5	1.43	-6	-1.0	-1.0	0.0	3
		25 mg	143	-0.6	1.37	-5	-1.0	0.0	0.0	3
	Week 12	12.5 mg	140	-0.7	1.49	-7	-2.0	-1.0	0.0	3
		25 mg	141	-0.7	1.36	-5	-2.0	-1.0	0.0	4
	Week 16	12.5 mg	138	-0.7	1.49	-5	-2.0	-1.0	0.0	5
		25 mg	135	-0.9	1.57	-7	-2.0	-1.0	0.0	4
	Week 20	12.5 mg	135	-0.7	1.61	-5	-2.0	-1.0	0.0	4
		25 mg	134	-0.6	1.75	-6	-2.0	-1.0	0.0	5
	Week 24	12.5 mg	134	-0.3	1.64	-5	-1.0	0.0	1.0	4
		25 mg	134	-0.4	1.87	-6	-1.0	0.0	1.0	6
	Week 28	12.5 mg	135	-0.3	1.59	-5	-1.0	0.0	1.0	3
		25 mg	132	-0.2	1.98	-9	-1.0	0.0	1.0	6
	Week 32	12.5 mg	135	-0.2	1.62	-5	-1.0	0.0	1.0	4
		25 mg	129	-0.0	2.07	-11	-1.0	0.0	1.0	7
	Week 36	12.5 mg	133	0.4	1.46	-5	0.0	0.0	1.0	5
		25 mg	129	0.7	1.97	-9	0.0	1.0	2.0	9
	Week 40	12.5 mg	132	0.6	1.64	-5	0.0	1.0	2.0	4
		25 mg	129	0.8	1.86	-7	0.0	1.0	2.0	8
	Week 44	12.5 mg	81	0.4	1.42	-4	-1.0	0.0	1.0	3
		25 mg	83	0.6	1.69	-5	0.0	1.0	2.0	6
	Week 48	12.5 mg	81	0.5	1.30	-3	0.0	1.0	1.0	3
		25 mg	83	0.7	1.92	-7	0.0	1.0	2.0	7
	Week 52	12.5 mg	81	0.6	1.45	-3	0.0	1.0	1.0	4
		25 mg	83	0.8	1.85	-7	0.0	1.0	2.0	6

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（12/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
MCH (pg/cell)	Week 2	12.5 mg	97	0.02	0.397	-1.3	-0.20	0.00	0.30	1.4
		25 mg	102	0.02	0.398	-0.9	-0.20	0.00	0.30	1.0
	Week 4	12.5 mg	135	-0.12	0.441	-1.4	-0.40	-0.10	0.20	1.3
		25 mg	138	-0.13	0.502	-2.4	-0.40	0.00	0.20	0.8
	Week 8	12.5 mg	141	-0.27	0.543	-1.9	-0.60	-0.20	0.10	1.1
		25 mg	143	-0.28	0.552	-2.9	-0.60	-0.20	0.00	1.0
	Week 12	12.5 mg	140	-0.38	0.542	-2.1	-0.70	-0.40	0.00	0.9
		25 mg	141	-0.40	0.532	-2.3	-0.70	-0.40	-0.10	0.9
	Week 16	12.5 mg	138	-0.43	0.540	-2.2	-0.70	-0.40	-0.20	1.4
		25 mg	135	-0.45	0.545	-2.2	-0.70	-0.40	-0.10	0.8
	Week 20	12.5 mg	135	-0.48	0.622	-2.5	-0.80	-0.50	-0.10	1.7
		25 mg	134	-0.47	0.651	-2.6	-0.80	-0.50	-0.10	1.0
	Week 24	12.5 mg	134	-0.44	0.627	-2.3	-0.90	-0.50	0.00	1.1
		25 mg	134	-0.41	0.708	-3.5	-0.70	-0.40	0.00	1.4
	Week 28	12.5 mg	135	-0.34	0.607	-2.6	-0.70	-0.40	0.10	1.4
		25 mg	132	-0.30	0.805	-4.6	-0.60	-0.20	0.20	2.3
	Week 32	12.5 mg	135	-0.22	0.629	-2.3	-0.60	-0.20	0.20	1.5
		25 mg	129	-0.15	0.803	-4.3	-0.50	-0.10	0.30	2.3
	Week 36	12.5 mg	133	0.05	0.610	-1.8	-0.30	0.10	0.40	1.5
		25 mg	129	0.08	0.780	-3.5	-0.30	0.10	0.50	2.5
	Week 40	12.5 mg	132	0.08	0.583	-1.6	-0.20	0.05	0.50	1.5
		25 mg	129	0.17	0.704	-3.1	-0.20	0.20	0.60	2.5
	Week 44	12.5 mg	81	0.11	0.490	-1.1	-0.20	0.10	0.40	1.3
		25 mg	83	0.22	0.752	-3.1	-0.10	0.20	0.80	2.6
	Week 48	12.5 mg	81	0.24	0.489	-1.0	0.00	0.30	0.50	1.7
		25 mg	83	0.43	0.739	-3.0	0.20	0.50	0.80	3.2
	Week 52	12.5 mg	81	0.29	0.570	-1.2	-0.10	0.30	0.60	1.7
		25 mg	83	0.42	0.766	-3.4	0.10	0.50	0.80	3.3

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-37　血液学的検査の評価時点別変化量（SYR-322/OCT-005 試験）（13/13）

Variable / Visit		Treatment	Summary Statistics							
			N	Mean	SD	Min	Q1	Median	Q3	Max
MCHC (%)	Week 2	12.5 mg	97	0.10	0.602	-1.3	-0.30	0.10	0.50	2.0
		25 mg	102	0.08	0.574	-1.1	-0.30	0.00	0.50	1.6
	Week 4	12.5 mg	135	-0.02	0.627	-2.2	-0.30	0.00	0.30	1.5
		25 mg	138	-0.01	0.580	-1.5	-0.40	0.00	0.40	1.7
	Week 8	12.5 mg	141	-0.10	0.680	-1.9	-0.50	-0.10	0.30	1.4
		25 mg	143	-0.10	0.665	-1.9	-0.60	-0.10	0.40	1.6
	Week 12	12.5 mg	140	-0.15	0.680	-1.7	-0.60	-0.15	0.30	1.8
		25 mg	141	-0.16	0.596	-1.6	-0.60	-0.20	0.20	1.8
	Week 16	12.5 mg	138	-0.18	0.628	-1.7	-0.60	-0.15	0.30	1.4
		25 mg	135	-0.19	0.619	-1.8	-0.60	-0.20	0.30	1.0
	Week 20	12.5 mg	135	-0.26	0.625	-1.9	-0.70	-0.20	0.20	1.6
		25 mg	134	-0.28	0.688	-2.0	-0.80	-0.40	0.20	1.4
	Week 24	12.5 mg	134	-0.38	0.624	-1.8	-0.80	-0.40	0.10	1.1
		25 mg	134	-0.31	0.557	-1.8	-0.60	-0.30	0.00	1.3
	Week 28	12.5 mg	135	-0.24	0.535	-1.8	-0.60	-0.20	0.20	1.3
		25 mg	132	-0.27	0.658	-2.2	-0.70	-0.20	0.20	1.4
	Week 32	12.5 mg	135	-0.17	0.602	-1.5	-0.60	-0.20	0.20	1.3
		25 mg	129	-0.17	0.528	-1.7	-0.60	-0.10	0.20	1.0
	Week 36	12.5 mg	133	-0.10	0.575	-1.4	-0.50	-0.10	0.30	1.3
		25 mg	129	-0.18	0.560	-1.7	-0.50	-0.20	0.20	1.1
	Week 40	12.5 mg	132	-0.16	0.603	-1.5	-0.60	-0.10	0.30	1.2
		25 mg	129	-0.11	0.528	-1.3	-0.50	0.00	0.20	1.2
	Week 44	12.5 mg	81	-0.04	0.502	-1.2	-0.40	-0.10	0.30	1.2
		25 mg	83	-0.03	0.517	-1.4	-0.40	0.10	0.30	1.2
	Week 48	12.5 mg	81	0.08	0.515	-1.0	-0.30	0.10	0.40	1.1
		25 mg	83	0.20	0.532	-1.1	-0.20	0.20	0.50	1.5
	Week 52	12.5 mg	81	0.10	0.651	-1.4	-0.30	0.20	0.60	1.5
		25 mg	83	0.16	0.524	-1.2	-0.20	0.10	0.50	1.6

総括報告書（5.3.5.2-1）表 14.4.10

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（1/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
RBC	Week 2	Lower	8	6	-	14	5	5	-	10
		Normal	2	78	2	82	2	89	1	92
		Upper	-	1	-	1	-	-	-	-
		Total	10	85	2	97	7	94	1	102
	Week 4	Lower	11	6	-	17	7	5	-	12
		Normal	3	112	1	116	1	120	1	122
		Upper	-	-	2	2	-	3	1	4
		Total	14	118	3	135	8	128	2	138
	Week 8	Lower	10	8	-	18	7	4	-	11
		Normal	4	115	1	120	1	128	1	130
		Upper	-	1	2	3	-	1	1	2
		Total	14	124	3	141	8	133	2	143
	Week 12	Lower	8	7	-	15	6	1	-	7
		Normal	6	116	-	122	2	126	1	129
		Upper	-	-	3	3	-	4	1	5
		Total	14	123	3	140	8	131	2	141
	Week 16	Lower	12	7	-	19	5	4	-	9
		Normal	2	113	1	116	3	121	1	125
		Upper	-	1	2	3	-	-	1	1
		Total	14	121	3	138	8	125	2	135
	Week 20	Lower	12	4	-	16	6	7	-	13
		Normal	2	113	1	116	2	116	1	119
		Upper	-	1	2	3	-	1	1	2
		Total	14	118	3	135	8	124	2	134
	Week 24	Lower	9	8	-	17	6	4	-	10
		Normal	5	109	-	114	2	118	1	121
		Upper	-	1	2	3	-	2	1	3
		Total	14	118	2	134	8	124	2	134

総括報告書（5.3.5.2-1）表 14.4.11

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（2/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
RBC	Week 28	Lower	11	10	-	21	7	7	-	14
		Normal	3	108	-	111	1	112	1	114
		Upper	-	-	3	3	-	3	1	4
		Total	14	118	3	135	8	122	2	132
	Week 32	Lower	12	8	-	20	7	4	-	11
		Normal	2	110	1	113	1	115	1	117
		Upper	-	-	2	2	-	-	1	1
		Total	14	118	3	135	8	119	2	129
	Week 36	Lower	11	6	-	17	5	5	-	10
		Normal	3	111	-	114	3	112	1	116
		Upper	-	-	2	2	-	2	1	3
		Total	14	117	2	133	8	119	2	129
	Week 40	Lower	11	8	-	19	6	5	-	11
		Normal	2	108	2	112	2	111	1	114
		Upper	-	-	1	1	-	3	1	4
		Total	13	116	3	132	8	119	2	129
	Week 44	Lower	8	3	-	11	5	4	-	9
		Normal	1	67	1	69	2	70	1	73
		Upper	-	-	1	1	-	1	-	1
		Total	9	70	2	81	7	75	1	83
	Week 48	Lower	8	1	-	9	6	3	-	9
		Normal	1	69	1	71	1	70	1	72
		Upper	-	-	1	1	-	2	-	2
		Total	9	70	2	81	7	75	1	83
	Week 52	Lower	6	3	-	9	6	3	-	9
		Normal	3	66	1	70	1	70	1	72
		Upper	-	1	1	2	-	2	-	2
		Total	9	70	2	81	7	75	1	83

総括報告書（5.3.5.2-1）表 14.4.11

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（3/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
WBC	Week 2	Lower	1	-	-	1	-	1	-	1
		Normal	-	78	6	84	1	85	3	89
		Upper	-	5	7	12	-	6	6	12
		Total	1	83	13	97	1	92	9	102
	Week 4	Lower	-	1	-	1	-	-	-	-
		Normal	1	108	10	119	1	113	5	119
		Upper	-	8	7	15	-	10	9	19
		Total	1	117	17	135	1	123	14	138
	Week 8	Lower	-	-	-	-	-	-	-	-
		Normal	1	115	8	124	1	118	6	125
		Upper	-	8	9	17	-	10	8	18
		Total	1	123	17	141	1	128	14	143
	Week 12	Lower	-	-	-	-	-	-	-	-
		Normal	1	110	7	118	1	115	7	123
		Upper	-	12	10	22	-	11	7	18
		Total	1	122	17	140	1	126	14	141
	Week 16	Lower	-	-	-	-	-	-	-	-
		Normal	1	112	6	119	1	114	3	118
		Upper	-	8	11	19	-	9	8	17
		Total	1	120	17	138	1	123	11	135
	Week 20	Lower	-	-	-	-	-	-	-	-
		Normal	1	108	7	116	-	112	3	115
		Upper	-	10	9	19	-	11	8	19
		Total	1	118	16	135	-	123	11	134
	Week 24	Lower	-	-	-	-	-	1	-	1
		Normal	1	108	8	117	-	117	2	119
		Upper	-	10	7	17	-	5	9	14
		Total	1	118	15	134	-	123	11	134

総括報告書（5.3.5.2-1）表 14.4.11

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（4/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
WBC	Week 28	Lower	-	1	-	1	-	-	-	-
		Normal	1	103	8	112	-	112	5	117
		Upper	-	14	8	22	-	9	6	15
		Total	1	118	16	135	-	121	11	132
	Week 32	Lower	-	-	-	-	-	-	-	-
		Normal	1	109	9	119	-	104	5	109
		Upper	-	9	7	16	-	14	6	20
		Total	1	118	16	135	-	118	11	129
	Week 36	Lower	-	-	-	-	-	-	-	-
		Normal	1	108	7	116	-	108	6	114
		Upper	-	9	8	17	-	10	5	15
		Total	1	117	15	133	-	118	11	129
	Week 40	Lower	-	-	-	-	-	-	-	-
		Normal	1	105	11	117	-	108	4	112
		Upper	-	10	5	15	-	10	7	17
		Total	1	115	16	132	-	118	11	129
	Week 44	Lower	-	-	-	-	-	-	-	-
		Normal	1	63	4	68	-	70	2	72
		Upper	-	6	7	13	-	7	4	11
		Total	1	69	11	81	-	77	6	83
	Week 48	Lower	-	1	-	1	-	-	-	-
		Normal	1	64	4	69	-	71	4	75
		Upper	-	4	7	11	-	6	2	8
		Total	1	69	11	81	-	77	6	83
	Week 52	Lower	-	1	-	1	-	-	-	-
		Normal	1	64	7	72	-	75	3	78
		Upper	-	4	4	8	-	2	3	5
		Total	1	69	11	81	-	77	6	83

総括報告書（5.3.5.2-1）表 14.4.11

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（5/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Hemoglobin	Week 2	Lower	2	4	-	6	3	3	-	6
		Normal	6	82	2	90	1	91	2	94
		Upper	-	1	-	1	-	1	1	2
		Total	8	87	2	97	4	95	3	102
	Week 4	Lower	7	6	-	13	3	4	-	7
		Normal	4	113	2	119	1	123	4	128
		Upper	-	1	2	3	-	2	1	3
		Total	11	120	4	135	4	129	5	138
	Week 8	Lower	6	5	-	11	2	7	-	9
		Normal	5	118	2	125	2	126	4	132
		Upper	-	3	2	5	-	1	1	2
		Total	11	126	4	141	4	134	5	143
	Week 12	Lower	5	10	-	15	3	1	-	4
		Normal	6	113	1	120	1	131	3	135
		Upper	-	2	3	5	-	-	2	2
		Total	11	125	4	140	4	132	5	141
	Week 16	Lower	6	9	-	15	1	8	-	9
		Normal	5	114	3	122	1	119	4	124
		Upper	-	-	1	1	-	1	1	2
		Total	11	123	4	138	2	128	5	135
	Week 20	Lower	6	11	-	17	1	7	-	8
		Normal	5	109	2	116	1	119	4	124
		Upper	-	-	2	2	-	1	1	2
		Total	11	120	4	135	2	127	5	134
	Week 24	Lower	7	9	-	16	1	9	-	10
		Normal	4	111	2	117	1	117	2	120
		Upper	-	-	1	1	-	1	3	4
		Total	11	120	3	134	2	127	5	134

総括報告書（5.3.5.2-1）表 14.4.11

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（6/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Hemoglobin	Week 28	Lower	9	8	-	17	1	8	-	9
		Normal	2	112	2	116	1	116	4	121
		Upper	-	-	2	2	-	1	1	2
		Total	11	120	4	135	2	125	5	132
	Week 32	Lower	8	7	-	15	1	5	-	6
		Normal	3	112	2	117	1	117	5	123
		Upper	-	1	2	3	-	-	-	-
		Total	11	120	4	135	2	122	5	129
	Week 36	Lower	5	5	-	10	1	4	-	5
		Normal	6	112	1	119	1	117	1	119
		Upper	-	2	2	4	-	1	4	5
		Total	11	119	3	133	2	122	5	129
	Week 40	Lower	5	7	-	12	1	4	-	5
		Normal	6	110	2	118	1	116	2	119
		Upper	-	-	2	2	-	2	3	5
		Total	11	117	4	132	2	122	5	129
	Week 44	Lower	4	2	-	6	1	5	-	6
		Normal	4	68	1	73	1	71	1	73
		Upper	-	1	1	2	-	2	2	4
		Total	8	71	2	81	2	78	3	83
	Week 48	Lower	2	1	-	3	1	3	-	4
		Normal	6	69	1	76	1	72	-	73
		Upper	-	1	1	2	-	3	3	6
		Total	8	71	2	81	2	78	3	83
	Week 52	Lower	5	2	-	7	1	4	-	5
		Normal	3	67	1	71	1	72	-	73
		Upper	-	2	1	3	-	2	3	5
		Total	8	71	2	81	2	78	3	83

総括報告書（5.3.5.2-1）表 14.4.11

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（7/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Hematocrit	Week 2	Lower	5	5	-	10	4	3	-	7
		Normal	5	79	2	86	1	92	-	93
		Upper	-	1	-	1	-	1	1	2
		Total	10	85	2	97	5	96	1	102
	Week 4	Lower	11	9	-	20	4	3	-	7
		Normal	4	107	3	114	1	128	-	129
		Upper	-	-	1	1	-	1	1	2
		Total	15	116	4	135	5	132	1	138
	Week 8	Lower	11	4	-	15	3	5	-	8
		Normal	4	117	3	124	2	132	-	134
		Upper	-	1	1	2	-	-	1	1
		Total	15	122	4	141	5	137	1	143
	Week 12	Lower	9	8	-	17	4	5	-	9
		Normal	6	113	3	122	1	130	-	131
		Upper	-	-	1	1	-	-	1	1
		Total	15	121	4	140	5	135	1	141
	Week 16	Lower	9	8	-	17	3	8	-	11
		Normal	6	111	3	120	-	123	1	124
		Upper	-	-	1	1	-	-	-	-
		Total	15	119	4	138	3	131	1	135
	Week 20	Lower	11	11	-	22	2	10	-	12
		Normal	4	105	3	112	1	120	-	121
		Upper	-	-	1	1	-	-	1	1
		Total	15	116	4	135	3	130	1	134
	Week 24	Lower	9	8	-	17	2	9	-	11
		Normal	6	108	2	116	1	119	-	120
		Upper	-	-	1	1	-	2	1	3
		Total	15	116	3	134	3	130	1	134

総括報告書（5.3.5.2-1）表 14.4.11

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（8/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Hematocrit	Week 28	Lower	12	11	-	23	2	7	-	9
		Normal	3	105	2	110	1	120	-	121
		Upper	-	-	2	2	-	1	1	2
		Total	15	116	4	135	3	128	1	132
	Week 32	Lower	10	11	-	21	2	4	-	6
		Normal	5	105	2	112	1	121	1	123
		Upper	-	-	2	2	-	-	-	-
		Total	15	116	4	135	3	125	1	129
	Week 36	Lower	7	3	-	10	2	5	-	7
		Normal	8	111	1	120	1	117	-	118
		Upper	-	1	2	3	-	3	1	4
		Total	15	115	3	133	3	125	1	129
	Week 40	Lower	9	4	-	13	2	3	-	5
		Normal	6	109	3	118	1	121	-	122
		Upper	-	-	1	1	-	1	1	2
		Total	15	113	4	132	3	125	1	129
	Week 44	Lower	6	2	-	8	2	5	-	7
		Normal	4	66	2	72	1	73	1	75
		Upper	-	1	-	1	-	1	-	1
		Total	10	69	2	81	3	79	1	83
	Week 48	Lower	5	2	-	7	2	3	-	5
		Normal	5	66	1	72	1	75	-	76
		Upper	-	1	1	2	-	1	1	2
		Total	10	69	2	81	3	79	1	83
	Week 52	Lower	6	3	-	9	3	3	-	6
		Normal	4	65	1	70	-	75	-	75
		Upper	-	1	1	2	-	1	1	2
		Total	10	69	2	81	3	79	1	83

総括報告書（5.3.5.2-1）表 14.4.11

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（9/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Platelet Count	Week 2	Lower	-	-	-	-	1	-	-	1
		Normal	-	78	3	81	2	88	2	92
		Upper	-	4	9	13	-	4	4	8
		Total	-	82	12	94	3	92	6	101
	Week 4	Lower	-	-	-	-	2	-	-	2
		Normal	-	113	4	117	2	121	2	125
		Upper	-	4	12	16	-	3	7	10
		Total	-	117	16	133	4	124	9	137
	Week 8	Lower	-	1	-	1	2	-	-	2
		Normal	-	117	6	123	1	127	3	131
		Upper	-	5	10	15	-	3	6	9
		Total	-	123	16	139	3	130	9	142
	Week 12	Lower	-	-	-	-	2	1	-	3
		Normal	-	117	6	123	1	125	4	130
		Upper	-	4	10	14	-	2	4	6
		Total	-	121	16	137	3	128	8	139
	Week 16	Lower	-	-	-	-	2	-	-	2
		Normal	-	118	3	121	1	121	4	126
		Upper	-	1	13	14	-	3	3	6
		Total	-	119	16	135	3	124	7	134
	Week 20	Lower	-	1	-	1	2	-	-	2
		Normal	-	112	6	118	1	121	4	126
		Upper	-	4	10	14	-	2	3	5
		Total	-	117	16	133	3	123	7	133
	Week 24	Lower	-	1	-	1	2	-	-	2
		Normal	-	112	8	120	1	121	5	127
		Upper	-	3	7	10	-	2	2	4
		Total	-	116	15	131	3	123	7	133

総括報告書（5.3.5.2-1）表 14.4.11

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（10/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Platelet Count	Week 28	Lower	-	-	-	-	2	-	-	2
		Normal	-	115	9	124	1	119	4	124
		Upper	-	2	7	9	-	3	2	5
		Total	-	117	16	133	3	122	6	131
	Week 32	Lower	-	-	-	-	2	1	-	3
		Normal	-	116	10	126	1	117	5	123
		Upper	-	-	6	6	-	1	1	2
		Total	-	116	16	132	3	119	6	128
	Week 36	Lower	-	2	-	2	2	1	-	3
		Normal	-	113	11	124	1	116	5	122
		Upper	-	1	4	5	-	2	1	3
		Total	-	116	15	131	3	119	6	128
	Week 40	Lower	-	1	-	1	2	2	-	4
		Normal	-	113	9	122	1	117	4	122
		Upper	-	1	6	7	-	-	2	2
		Total	-	115	15	130	3	119	6	128
	Week 44	Lower	-	1	-	1	1	-	-	1
		Normal	-	68	9	77	1	76	3	80
		Upper	-	-	2	2	-	1	-	1
		Total	-	69	11	80	2	77	3	82
	Week 48	Lower	-	1	-	1	1	1	-	2
		Normal	-	67	7	74	1	75	3	79
		Upper	-	-	4	4	-	1	-	1
		Total	-	68	11	79	2	77	3	82
	Week 52	Lower	-	1	-	1	1	1	-	2
		Normal	-	67	7	74	1	76	3	80
		Upper	-	1	4	5	-	-	-	-
		Total	-	69	11	80	2	77	3	82

総括報告書（5.3.5.2-1）表 14.4.11

表 2.7.4.7-付録-38　血液学的検査の正異判定のクロス表（SYR-322/OCT-005 試験）（11/26）

			12.5 mg				25 mg			
			Week 0				Week 0			
			Lower	Normal	Upper	Total	Lower	Normal	Upper	Total
Neutrophils	Week 2	Lower	-	-	-	-	2	-	-	2
		Normal	3	92	1	96	1	95	1	97
		Upper	-	1	-	1	-	1	2	3
		Total	3	93	1	97	3	96	3	102
	Week 4	Lower	-	2	-	2	3	-	-	3
		Normal	4	126	1	131	1	130	3	134
		Upper	-	2	-	2	-	1	-	1
		Total	4	130	1	135	4	131	3	138
	Week 8	Lower	-	2	-	2	3	-	-	3
		Normal	4	131	1	136	1	134	3	138
		Upper	-	3	-	3	-	2	-	2
		Total	4	136	1	141	4	136	3	143
	Week 12	Lower	-	3	-	3	3	-	-	3
		Normal	4	130	1	135	1	132	3	136
		Upper	-	2	-	2	-	2	-	2
		Total	4	135	1	140	4	134	3	141
	Week 16	Lower	1	2	-	3	1	3	-	4
		Normal	3	130	1	134	3	124	2	129
		Upper	-	1	-	1	-	2	-	2
		Total	4	133	1	138	4	129	2	135
	Week 20	Lower	-	1	-	1	2	2	-	4
		Normal	4	128	-	132	2	124	2	128
		Upper	-	2	-	2	-	2	-	2
		Total	4	131	-	135	4	128	2	134
	Week 24	Lower	-	1	-	1	3	1	-	4
		Normal	4	125	-	129	1	126	2	129
		Upper	-	4	-	4	-	1	-	1
		Total	4	130	-	134	4	128	2	134

総括報告書（5.3.5.2-1）表 14.4.11