Clinical Laboratory Parameters for the Crl:CD®(SD) BR Rats

INTRODUCTION:

The use of some form of measured diet, also referred to as dietary optimization, is becoming increasingly common in standard toxicology studies as it is thought to result in healthier animals than the traditional *ad libitum* feeding regimen (1,2,3,4,5). The data presented in this document were gathered from 10 toxicology studies of at least 13 weeks duration in which some form of dietary restriction was employed. All studies were performed in accordance with Good Laboratory Practice regulations of either the US Food and Drug Administration or the Environmental Protection Agency and/or the Standard Operating Procedures of the participating laboratory. All studies were performed in the United States or Europe by contract laboratories or industrial toxicology facilities and were designed to support in-house research or marketing permits.

PURPOSE:

The purpose of this monograph is to provide the study director and/or reviewing toxicologist with a range of normal or expected values for selected hematology and serum chemistry parameters obtained at various intervals in studies of at least 13 weeks duration. It is recognized that different analytical methods as well as environmental and technique related variables can influence the values obtained for a particular parameter. For these reasons, care should be taken in using these data which are not intended as a substitute for historical data collected within a single institution.

COMMON STUDY PARAMETERS:

The 10 studies included in this publication were initiated between January 1993 and July 1998 in three different facilities. All studies used Crl:CD(SD)BR rats from two different Charles River Laboratories production sites: animals in study A-H were from Raleigh, NC, and animals in studies I and J were from St. Louis, MO.

The rats in these studies were from control groups of dietary or gavage studies and were approximately 4 - 8 weeks of age at study initiation. Some groups were untreated and others received deionized water; 0.5% aqueous methylcellulose; 1.0 % aqueous methylcellulose; or 1.0 % polyethylene glycol as the vehicle control.

Rats included in this publication were singly housed in stainless steel wire mesh cages with free access to water. The animal rooms were generally maintained at average temperatures of 72 +/- 5 degrees Fahrenheit with an average relative humidity of 30-70%. A 12hr/12hr light/dark cycle was employed in all studies. Since these studies were conducted in different facilities, there was some variation in environmental conditions. However, the overall environmental conditions were not considered by those performing the studies to have had any effect on the overall quality or integrity of the studies. All rats received measured amounts of Purina PMI Certified Rodent Chow 5002 with a physiological fuel value of 3.4 kcal/g. The amount of feed consumed ranged from 16 to 21 grams for females and 21 to 25.2 grams for males. Therefore the calculated physiological fuel values per study ranged from 54.4 to 71.4 kcal/gram for females and 71.4 to 78.2 kcal/gram for males.

Clinical laboratory evaluations were performed at 4, 8 and/or 12 weeks in these studies. The rats were fasted overnight and blood was collected from the retro-orbital sinus in all studies. For studies A-J serum chemistry determinations were performed using a BMC Hitachi-Model 717 analyzer and hematology determinations were made using the Technicon H*1E analyzer by Bayer.

DATA PRESENTED:

The serum chemistry and hematology data are separated by sex and evaluation period and presented by individual study group. Study codes are consistent across all tables to allow the investigator to follow a particular group of animals throughout the 4 week, 8 week and 12 week evaluation periods. Studies I and J did not have serum chemistry or hematology evaluations at week 4 or 8. Therefore data from these studies is included only in the 12 week evaluation tables. In some studies, evaluations were performed during study week 13 rather than week 12. In these instances the data is included as a 12 week evaluation. Whenever necessary, results were converted to match the units more commonly used and presented here. Due to variations in methodology used to obtain these values and the intrinsic variations among studies and laboratories, it was not considered appropriate to combine individual study group means into overall means.

ABBREVIATIONS

A/G Ratio = albumin/globulin ratio
ALT = Alanine Aminotransferase
AST = Aspartate Aminotransferase
Mean Corp Hgb Conc = Mean Corpuscular Hemoglobin
Mean Corp Hgb = Mean Corpuscular Hemoglobin
Mean Corp Vol = Mean Corpuscular Volume
NA = Not Available

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Table 1: Summary of Hematological Parameters from Individual Studies at 4 Weeks – Males

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**		
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**		
Number of Animals	**15**		**15**		**15**		**15**		
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	
Erythrocytes, million/mm3	7.11	0.37	7.45	0.39	7.10	0.31	7.35	0.34	1
Hematocrit, %	41.8	1.9	44.2	1.7	41.3	1.5	42.5	1.4	2
Hemoglobin, gm/100 ml	13.9	0.7	14.4	0.5	14.5	0.5	14.4	0.5	3
Mean Corp Hgb Conc, gm/dl	33.4	0.5	32.5	0.5	35	0.4	33.9	0.4	4
Mean Corp Hgb, picograms	19.6	0.3	19.3	0.6	20.3	0.5	19.6	0.7	5
Mean Corp Vol, cubic microns	58.8	1.1	59.4	2.1	58.2	1.6	58	1.8	6
Leukocytes, 1000/mm3	13.53	3.53	9.62	2.45	12.06	1.79	15.69	2.66	7
Neutrophils, %	11.7	7.8	13.3	5.9	9.9	6.6	7	2.5	8
Neutrophils, cells/mm3	1665	1387	1246	513	1249	1118	1077	376	9
Lymphocytes, %	83.3	7.7	82.2	6.1	85.4	6.7	87.7	3	10
Lymphocytes, cells/mm3	11196	2865	7929	2221	10237	1259	13768	2445	11
Monocytes, %	2.7	0.9	2.2	0.7	2	0.5	2.4	0.6	12
Monocytes,cells/mm3	356	123	212	101	243	83	382	123	13
Eosinophils, %	1	0.6	0.9	0.4	0.8	0.5	0.9	0.4	14
Eosinophils, cells/mm3	123	57	80	33	95	68	143	60	15
Basophils, %	0.5	0.2	0.4	0.1	0.3	0.1	0.6	0.1	16
Basophils, cells/mm3	78	39	39	17	40	12	101	37	17
Large Unstained Cells, %	0.9	0.2	1.1	0.3	1.7	0.3	1.4	0.3	18
Large Unstained Cells, cells/mm3	120	55	112	54	201	48	219	77	19
Platelets, 1000/mm3	899	105	1022	145	952	77	945	114	20
Study Identification	**Study E**		**Study F**		**Study G**		**Study H**		
Study Start Date	**Feb-97**		**Jun-97**		**Oct-97**		**Jul-98**		
Number of Animals	**15**		**15**		**15**		**15**		
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	
Erythrocytes, million/mm3	7	0.34	6.76	0.26	6.96	0.36	7.03	0.28	1
Hematocrit, %	41.1	1.6	40.1	1.3	40.6	1.9	40.9	1.7	2
Hemoglobin, gm/100 ml	14.2	0.6	14	0.4	13.9	0.6	13.9	0.5	3
Mean Corp Hgb Conc, gm/dl	34.4	0.4	35	0.6	34.3	0.4	34	0.6	4
Mean Corp Hgb, picograms	20.2	0.5	20.8	0.7	20	0.6	19.8	0.6	5
Mean Corp Vol, cubic microns	58.8	1.7	59.4	1.6	58.3	1.6	58.2	1.4	6
Leukocytes, 1000/mm3	10.77	1.8	11.1	1.88	11.86	3.26	12.16	3.78	7
Neutrophils, %	7.8	1.7	7.7	2.4	7.6	2.6	8.1	2.6	8
Neutrophils, cells/mm3	842	224	840	261	854	249	927	264	9
Lymphocytes, %	87.2	2	86.9	2.8	86.9	2.4	86	3.2	10
Lymphocytes, cells/mm3	9396	1609	9660	1771	10357	3078	10516	3452	11
Monocytes, %	2.4	0.8	2.5	0.7	2.3	0.5	3.1	0.8	12
Monocytes,cells/mm3	264	93	281	90	276	90	366	139	13
Eosinophils, %	0.8	0.4	0.8	0.3	1	0.6	0.9	0.3	14
Eosinophils, cells/mm3	81	31	88	26	114	56	97	33	15
Basophils, %	0.4	0.1	0.3	0.1	0.4	0.1	0.4	0.1	16
Basophils, cells/mm3	43	18	37	11	53	29	50	33	17
Large Unstained Cells, %	1.3	0.3	1.7	0.4	1.7	0.4	1.6	0.4	18
Large Unstained Cells, cells/mm3	144	31	194	61	209	98	200	93	19
Platelets, 1000/mm3	964	121	1020	128	929	107	1015	126	20

Table 2: Summary of Hematological Parameters from Individual Studies at 4 Weeks – Females

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**	
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
Erythrocytes, million/mm3	7.41	0.29	7.15	0.29	7.1	0.32	7.51	0.37
Hematocrit, %	42.8	1.6	41.1	2	39.8	1.8	41.8	1.4
Hemoglobin, gm/100 ml	14.4	0.5	13.8	0.6	14.1	0.6	14.3	0.4
Mean Corp Hgb Conc, gm/dl	33.7	0.6	33.6	0.7	35.5	0.4	34.2	0.5
Mean Corp Hgb, picograms	19.5	0.4	19.3	0.6	19.9	0.5	19.1	0.6
Mean Corp Vol, cubic microns	57.8	1.4	57.6	1.5	56	1.5	55.7	1.6
Leukocytes, 1000/mm3	10.5	2.57	11.32	4.02	9.62	2.99	9.57	3.06
Neutrophils, %	10.6	3.6	13	6.6	6.6	2.6	5.9	2.2
Neutrophils, cells/mm3	1117	504	1442	771	610	203	583	337
Lymphocytes, %	84.5	3.8	82	7.3	89.4	3.3	89.5	3
Lymphocytes, cells/mm3	8855	2173	9295	3460	8629	2770	8546	2622
Monocytes, %	2.3	0.6	2.3	0.9	1.5	0.7	1.9	0.8
Monocytes, cells/mm3	238	85	266	151	144	72	181	95
Eosinophils, %	1.3	0.6	1.1	0.4	0.8	0.2	1.3	0.4
Eosinophils,cells/mm3	134	72	125	52	78	24	130	84
Basophils cells/mm3	50	22	60	37	31	15	43	23
Basophils, %	0.5	0.1	0.5	0.2	0.3	0.1	0.4	0.1
Large Unstained Cells, %	1	0.2	1.1	0.3	1.3	0.3	1	0.2
Large Unstained Cells, cells/mm3	105	39	136	77	128	64	92	31
Platelets, 1000/mm3	879	141	898	143	924	83	987	165
Study Identification	**Study E**		**Study F**		**Study G**		**Study H**	
Study Start Date	**Feb-97**		**Jun-97**		**Oct-97**		**Jul-98**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
Erythrocytes, million/mm3	7.28	0.27	6.89	0.29	7.21	0.27	6.97	0.38
Hematocrit, %	41	1.6	39.3	1.1	40.2	1.5	39.1	1.2
Hemoglobin, gm/100 ml	14.5	0.4	14	0.4	14.1	0.4	13.8	0.4
Mean Corp Hgb Conc, gm/dl	35.3	0.5	35.6	0.3	35	0.3	35.3	0.3
Mean Corp Hgb, picograms	19.9	0.5	20.3	0.5	19.5	0.6	19.8	0.7
Mean Corp Vol, cubic microns	56.4	1.6	57.2	1.2	55.8	1.7	56.1	1.8
Leukocytes, 1000/mm3	10.57	1.47	11.7	2.94	8.94	2.98	7.55	1.87
Neutrophils, %	6.3	2.4	6.5	1.9	7.9	4.5	7.1	2.4
Neutrophils, cells/mm3	658	273	734	206	686	386	520	188
Lymphocytes, %	89.1	2.7	88.2	2.1	86.6	4.9	87.3	2.7
Lymphocytes, cells/mm3	9419	1355	10354	2720	7754	2707	6616	1721
Monocytes, %	2	0.4	2.3	0.4	2.4	0.6	3	0.8
Monocytes, cells/mm3	219	62	265	65	220	110	221	84
Eosinophils, %	0.9	0.3	1	0.5	1.4	0.4	1	0.3
Eosinophils,cells/mm3	94	28	111	49	118	41	70	22
Basophils cells/mm3	42	14	40	20	33	20	23	12
Basophils, %	0.4	0.1	0.3	0.1	0.3	0.1	0.3	0.1
Large Unstained Cells, %	1.3	0.2	1.6	0.5	1.4	0.3	1.3	0.3
Large Unstained Cells, cells/mm3	136	36	201	102	128	77	102	35
Platelets, 1000/mm3	988	126	969	85	938	111	967	67

Table 3: Summary of Hematological Parameters from Individual Studies at 8 Weeks – Males

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**	
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
Erythrocytes, million/mm3	8.08	0.3	7.89	0.45	8.19	0.29	8.19	0.34
Hematocrit, %	44.1	1.7	42.3	1.9	43.8	1.8	45.9	1.3
Hemoglobin, gm/100 ml	15	0.5	14.6	0.6	15.3	0.6	15	0.4
Mean Corp Hgb Conc, gm/dl	34.1	0.6	34.5	0.4	34.9	0.4	32.7	0.5
Mean Corp Hgb, picograms	18.6	0.4	18.6	0.7	18.7	0.4	18.3	0.6
Mean Corp Vol, cubic microns	54.5	1	53.7	1.8	53.5	1.4	56.1	1.4
Leukocytes, 1000/mm3	12.19	2.42	11.79	2.59	11.83	3.12	14.01	2.21
Neutrophils, %	9.9	3.5	14.5	7.3	10.8	6.8	8.5	3.1
Neutrophils, cells/mm3	1183	386	1701	984	1348	1276	1148	273
Lymphocytes, %	85.1	3.7	80.2	7.3	83.7	7	86	3.6
Lymphocytes, cells/mm3	10406	2233	9472	2314	9813	2261	12095	2199
Monocytes, %	2.1	0.6	2.4	0.6	2.4	0.5	2.6	0.7
Monocytes,cells/mm3	261	81	282	85	287	139	358	108
Eosinophils, %	1.2	0.6	1	0.5	1.1	0.4	1.2	0.5
Eosinophils, cells/mm3	137	65	119	52	134	63	163	63
Basophils, %	0.5	0.1	0.5	0.1	0.3	0.1	0.5	0.1
Basophils, cells/mm3	65	23	58	29	40	22	77	22
Large Unstained Cells, %	1.1	0.2	1.4	0.4	1.7	0.4	1.3	0.3
Large Unstained Cells, cells/mm3	139	41	160	54	206	100	177	56
Platelets, 1000/mm3	809	115	827	100	807	69	853	93
Study Identification	**Study E**		**Study F**		**Study G**		**Study H**	
Study Start Date	**Feb-97**		**Jun-97**		**Oct-97**		**Jul-98**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
Erythrocytes, million/mm3	8.03	0.35	7.78	0.26	7.89	0.29	7.77	0.29
Hematocrit, %	43.4	1.6	42.3	1.2	42.5	1.2	41.2	1.8
Hemoglobin, gm/100 ml	15.1	0.5	15.1	0.4	14.8	0.4	14.4	0.6
Mean Corp Hgb Conc, gm/dl	35	0.5	35.7	0.5	34.9	0.4	35	0.5
Mean Corp Hgb, picograms	18.9	0.5	19.4	0.8	18.8	0.5	18.6	0.4
Mean Corp Vol, cubic microns	54	1.6	54.4	1.9	53.9	1.5	53	1.3
Leukocytes, 1000/mm3	10.09	1.57	11.09	2.76	10.78	2.83	12.8	4.58
Neutrophils, %	9	2.5	9.6	4.7	8.6	4.7	8.2	2.3
Neutrophils, cells/mm3	908	307	1070	628	872	407	991	312
Lymphocytes, %	85.2	2.9	84.6	6	85.6	4.8	84.7	3.2
Lymphocytes, cells/mm3	8598	1386	9375	2443	9277	2703	10890	4118
Monocytes, %	2.5	0.8	2.6	1.2	2.6	0.5	3.4	1.1
Monocytes,cells/mm3	249	81	292	146	289	112	425	203
Eosinophils, %	1.3	0.6	1	0.4	1.5	1.1	1.3	0.6
Eosinophils, cells/mm3	129	55	113	36	144	75	158	72
Basophils, %	0.4	0.1	0.3	0.1	0.4	0.1	0.4	0.2
Basophils, cells/mm3	39	11	34	20	43	23	63	44
Large Unstained Cells, %	1.6	0.3	1.8	0.7	1.4	0.3	2	0.6
Large Unstained Cells, cells/mm3	168	49	205	110	154	69	265	147
Platelets, 1000/mm3	837	104	820	91	809	86	812	91

Table 4: Summary of Hematological Parameters from Individual Studies at 8 Weeks – Females

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**	
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
Erythrocytes, million/mm3	7.58	0.23	7.28	0.3	7.59	0.38	7.5	0.39
Hematocrit, %	42	1.3	9.6	1.8	40.7	1.8	42.3	2.1
Hemoglobin, gm/100 ml	14.5	0.5	14	0.6	14.5	0.6	13.9	0.6
Mean Corp Hgb Conc, gm/dl	34.5	0.5	35.3	0.4	35.6	0.4	32.8	0.5
Mean Corp Hgb, picograms	19.1	0.4	19.2	0.5	19.1	0.5	18.6	0.5
Mean Corp Vol, cubic microns	55.4	1.2	54.4	1.4	53.6	1.3	56.5	1.5
Leukocytes, 1000/mm3	10.48	3.44	9.91	3.37	8.29	2.14	9.01	3.31
Neutrophils, %	13	7.6	11.5	6.6	8.8	4.5	9	4.3
Neutrophils, cells/mm3	1398	1015	1133	663	727	386	811	530
Lymphocytes, %	82.3	8.2	83.7	6.6	86.5	4.7	86.2	5
Lymphocytes, cells/mm3	8579	2800	8288	2843	7174	1893	7772	2935
Monocytes, %	2.3	0.7	2.2	0.7	2	0.6	1.9	0.6
Monocytes, cells/mm3	243	123	222	100	161	55	171	87
Eosinophils, %	1	0.4	1	0.3	1.1	0.6	1.4	0.5
Eosinophils,cells/mm3	106	56	100	34	94	61	122	49
Basophils cells/mm3	50	26	45	31	23	10	35	23
Basophils, %	0.4	0.1	0.4	0.1	0.3	0.1	0.4	0.1
Large Unstained Cells, %	1	0.2	1.2	0.3	1.3	0.2	1.1	0.4
Large Unstained Cells, cells/mm3	107	46	122	54	111	34	106	74
Platelets, 1000/mm3	823	130	797	88	798	82	868	129
Study Identification	**Study E**		**Study F**		**Study G**		**Study H**	
Study Start Date	**Feb-97**		**Jun-97**		**Oct-97**		**Jul-98**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
Erythrocytes, million/mm3	7.51	0.27	7.23	0.23	7.62	0.24	7.21	0.42
Hematocrit, %	41.1	1	39.6	1.2	40.9	1.5	39	1.6
Hemoglobin, gm/100 ml	14.6	0.3	14.3	0.4	14.4	0.6	13.7	0.5
Mean Corp Hgb Conc, gm/dl	35.5	0.3	36.2	0.6	35.1	0.4	35.1	0.4
Mean Corp Hgb, picograms	19.4	0.6	19.8	0.5	18.9	0.6	19	0.7
Mean Corp Vol, cubic microns	54.8	1.7	54.8	1.8	53.7	1.8	54.3	1.8
Leukocytes, 1000/mm3	10.33	2.24	10.7	2.7	8.12	1.95	7.44	2.1
Neutrophils, %	7.7	3.5	6.8	3.9	7.5	2.9	7.1	2.8
Neutrophils, cells/mm3	791	390	719	455	616	307	542	313
Lymphocytes, %	86.9	3.5	88.4	4.7	86.8	3.2	86.7	3.8
Lymphocytes, cells/mm3	8984	1977	9470	2516	7040	1618	6424	1743
Monocytes, %	2.3	0.5	1.9	0.8	2.6	0.6	3.1	1.1
Monocytes, cells/mm3	232	64	205	101	208	70	232	118
Eosinophils, %	1.2	0.6	1.1	0.6	1.5	0.8	1.1	0.3
Eosinophils,cells/mm3	123	69	104	39	114	51	85	36
Basophils cells/mm3	39	22	37	17	27	11	24	16
Basophils, %	0.4	0.1	0.3	0.1	0.3	0.1	0.3	0.1
Large Unstained Cells, %	1.6	0.3	1.5	0.5	1.3	0.4	1.7	0.3
Large Unstained Cells, cells/mm3	164	54	166	73	109	73	132	53
Platelets, 1000/mm3	870	134	863	116	827	89	868	88

Table 5: Summary of Hematological Parameters from Individual Studies at 12 Weeks – Males

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**		**Study E**	
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**		**Feb-97**	
Number of Animals	**15**		**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
Erythrocytes, million/mm3	8.24	0.34	8.32	0.28	7.89	0.59	8.33	0.37	8.39	0.33
Hematocrit, %	43.9	1.5	43.6	1.3	41.7	3	46	1.6	44.1	1.5
Hemoglobin, gm/100 ml	14.6	0.4	15.1	0.5	14.7	1.1	15.2	0.4	15.3	0.5
Mean Corp Hgb Conc, gm/dl	33.2	0.6	34.7	0.5	35.3	0.6	33	0.5	34.8	0.5
Mean Corp Hgb, picograms	17.7	0.5	18.2	0.6	18.7	0.4	18.2	0.5	18.3	0.4
Mean Corp Vol, cubic microns	53.2	0.9	52.5	1.5	52.9	1.4	55.3	1.5	52.5	1.4
Leukocytes, 1000/mm3	11.48	1.43	11.88	2.26	11.21	2.79	10.46	1.42	9.87	2.38
Neutrophils, %	12.4	5.7	13.6	7.7	12.6	10	10.5	3.9	9.6	2.2
Neutrophils, cells/mm3	1398	590	1572	818	1646	2244	1070	299	945	309
Lymphocytes, %	82.8	6.1	80.1	7.7	80.4	10.1	83	4.6	84.3	2.9
Lymphocytes, cells/mm3	9531	1512	9562	2280	8785	955	8720	1460	8327	2076
Monocytes, %	1.8	0.6	2.7	0.6	3.4	0.6	3.1	0.7	2.8	0.9
Monocytes,cells/mm3	212	78	315	99	379	114	317	68	279	120
Eosinophils, %	1.3	0.5	1.4	0.6	1.2	0.5	1.6	0.6	1.5	0.7
Eosinophils, cells/mm3	156	67	162	74	137	56	163	66	141	55
Basophils, %	0.5	0.1	0.5	0.1	0.3	0.1	0.4	0.1	0.3	0.1
Basophils, cells/mm3	58	17	61	27	34	12	44	14	34	16
Large Unstained Cells, %	1.1	0.2	1.8	0.5	2.1	0.4	1.4	0.4	1.4	0.3
Large Unstained Cells, cells/mm3	127	29	212	88	234	89	144	43	143	50
Platelets, 1000/mm3	800	110	835	101	852	124	847	123	855	81
Study Identification	**Study F**		**Study G**		**Study H**		**Study I**		**Study J**	
Study Start Date	**Jun-97**		**Oct-97**		**Jul-98**		**Mar-93**		**Mar-93**	
Number of Animals	**15**		**15**		**15**		**24**		**25**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
Erythrocytes, million/mm3	8.05	0.38	8.24	0.3	8.19	0.26	8.9	0.4	8.7	0.4
Hematocrit, %	42.7	1.5	43.2	1.1	42.3	1.4	49.2	1.7	48.3	1.5
Hemoglobin, gm/100 ml	14.9	0.6	15	0.3	14.8	0.4	16.6	0.5	16.5	1.5
Mean Corp Hgb Conc, gm/dl	35	0.3	34.8	0.4	35.1	0.5	33.7	0.7	34.1	0.6
Mean Corp Hgb, picograms	18.6	0.6	18.3	0.6	18.1	0.4	18.7	0.7	18.9	0.7
Mean Corp Vol, cubic microns	53.1	1.7	52.5	1.6	51.7	1.2	55.5	1.7	55.4	1.8
Leukocytes, 1000/mm3	10.9	2.79	9.78	2.64	12.9	4.38	12.2	3.1	11.8	3
Neutrophils, %	10.8	3.6	9.5	3.1	10.8	4	9	3	12.3	6
Neutrophils, cells/mm3	1150	390	908	303	1349	647	1542	698	1288	692
Lymphocytes, %	82.9	4.2	84.1	3.3	80.7	5.9	87.1	3.5	83.9	6.1
Lymphocytes, cells/mm3	9071	2539	8255	2406	10453	3739	10654	2846	9868	2672
Monocytes, %	2.8	0.8	2.9	0.6	4.1	1.6	1.1	0.6	1.3	0.6
Monocytes,cells/mm3	299	105	286	113	524	273	136	96	149	86
Eosinophils, %	1.3	0.6	2	1.2	1.4	0.7	0.7	0.4	0.8	0.3
Eosinophils, cells/mm3	137	53	176	83	178	88	81	50	63	43
Basophils, %	0.3	0.1	0.3	0.1	0.4	0.1	0.5	0.3	0.5	0.2
Basophils, cells/mm3	37	19	27	16	60	34	63	43	63	39
Large Unstained Cells, %	1.8	0.4	1.3	0.3	2.6	1	1.5	0.7	1.3	0.7
Large Unstained Cells, cells/mm3	201	71	126	52	332	180	190	112	157	107
Platelets, 1000/mm3	821	87	765	107	865	86	795	116	795	99

Table 6: Summary of Hematological Parameters from Individual Studies at 12 Weeks – Females

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**		**Study E**	
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**		**Feb-97**	
Number of Animals	**15**		**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
Erythrocytes, million/mm3	7.23	0.3	7.47	0.24	7.43	0.3	7.74	0.37	7.54	0.27
Hematocrit, %	39.7	1.8	40.6	0.9	40.6	1.2	44	1.9	40.5	1.3
Hemoglobin, gm/100 ml	13.5	0.5	14.3	0.5	14.5	0.6	14.3	0.6	14.6	0.4
Mean Corp Hgb Conc, gm/dl	34.1	0.5	35.1	0.5	35.7	0.5	32.6	0.4	36	0.5
Mean Corp Hgb, picograms	18.7	0.4	19.1	0.7	19.5	0.5	18.5	0.5	19.3	0.6
Mean Corp Vol, cubic microns	54.9	1.2	54.4	1.4	54.7	1.5	56.9	1.7	53.7	1.6
Leukocytes, 1000/mm3	7.91	2.35	10.69	3.33	8.17	1.44	7.58	2.35	8.22	1.65
Neutrophils, %	10.3	5.6	14.2	7.9	9	3.6	10.7	8.5	7.9	2.6
Neutrophils, cells/mm3	869	681	1535	1029	711	231	905	1140	635	193
Lymphocytes, %	85.4	6.2	80.6	8.6	85.3	4.2	84	9.4	87	3
Lymphocytes, cells/mm3	6697	1837	8601	2895	6991	1416	6259	1711	7161	1533
Monocytes, %	1.9	0.6	2.2	1	2.5	0.9	2.4	1.1	2.2	0.6
Monocytes, cells/mm3	155	72	235	121	201	67	195	140	174	40
Eosinophils, %	1.2	0.5	1.2	0.5	1.4	0.5	1.4	0.5	1.4	0.6
Eosinophils,cells/mm3	93	35	127	52	114	55	104	47	112	57
Basophils cells/mm3	34	21	51	29	21	12	24	9	24	9
Basophils, %	0.4	0.1	0.4	0.1	0.2	0.1	0.3	0.1	0.3	0.1
Large Unstained Cells, %	0.8	0.2	1.3	0.2	1.5	0.3	1.2	0.4	1.4	0.3
Large Unstained Cells, cells/mm3	67	29	145	56	125	32	92	48	112	29
Platelets, 1000/mm3	817	132	787	102	815	93	818	152	877	132
Study Identification	**Study F**		**Study G**		**Study H**		**Study I**		**Study J**	
Study Start Date	**Jun-97**		**Oct-97**		**Jul-98**		**Mar-93**		**Mar-93**	
Number of Animals	**15**		**15**		**15**		**24**		**25**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
Erythrocytes, million/mm3	7.5	0.26	7.62	0.39	7.41	0.43	8.02	0.4	8.02	0.4
Hematocrit, %	40.8	1.3	40.8	1.6	39.6	1.6	44.4	2.2	44.5	2.3
Hemoglobin, gm/100 ml	14.5	0.5	14.3	0.5	14	0.5	15.4	0.8	15.4	0.8
Mean Corp Hgb Conc, gm/dl	35.5	0.3	35	0.3	35.4	0.5	34.6	0.6	34.5	0.6
Mean Corp Hgb, picograms	19.3	0.6	18.8	0.6	18.9	0.7	19.2	0.5	19.2	0.6
Mean Corp Vol, cubic microns	54.4	1.5	53.6	1.7	53.5	1.9	55.4	1.3	55.5	1.2
Leukocytes, 1000/mm3	9.37	2.17	7.5	2.64	7.57	1.55	10.63	2.99	10.27	3.22
Neutrophils, %	9.1	5.2	9.5	3.8	7.7	2	8.7	3.4	10	5.7
Neutrophils, cells/mm3	832	524	743	534	577	172	1800	853	1576	724
Lymphocytes, %	84.9	6.3	84.7	4.5	85.1	2.3	86.8	3.6	86	5.8
Lymphocytes, cells/mm3	7982	2063	6324	2078	6443	1358	9245	2730	8876	3054
Monocytes, %	2.7	1.1	2.8	0.9	3.3	1.1	1.5	0.6	1.4	0.7
Monocytes, cells/mm3	254	126	205	73	250	98	150	69	146	82
Eosinophils, %	1.3	0.6	1.5	0.7	1.6	0.5	0.8	0.3	0.6	0.3
Eosinophils,cells/mm3	112	46	110	54	120	42	79	37	60	40
Basophils cells/mm3	27	11	21	14	24	9	54	34	50	30
Basophils, %	0.3	0.1	0.3	0.1	0.3	0.1	0.5	0.2	0.5	0.2
Large Unstained Cells, %	1.7	0.5	1.2	0.3	2	0.5	1.8	0.9	1.6	0.7
Large Unstained Cells, cells/mm3	162	61	94	66	156	54	193	107	160	88
Platelets, 1000/mm3	832	110	790	110	880	57	808	123	791	124

Table 7: Summary of Serum Chemistry Parameters from Individual Studies at 4 Weeks – Males

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**		
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**		
Number of Animals	**15**		**15**		**15**		**15**		
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	
A/G Ratio	1.4	0.1	1.4	0.1	1.3	0.1	1.4	0.1	
Albumin, g/dl	3.4	0.1	3.4	0.1	3.2	0.1	3.5	0.1	
Alkaline Phosphatase, u/l	255	50	219	35	212	59	225	49	
ALT, u/l	35	4	29	4	29	5	28	5	
AST, u/l	113	20	102	15	101	17	116	23	
Calcium, mg/dl	9.9	0.2	9.4	0.2	9.7	0.2	10	0.3	
Chloride, mEq/l	104	1	102	1	104	1	103	1	
Cholesterol Total, mg/dl	64	10	65	11	65	12	64	6	
Creatinine, mg/dl	0.6	0.1	0.5	0	0.5	0.1	0.6	0.1	
Glucose, mg/dl	158	20	138	16	144	22	162	22	
Phosphorus, mg/dl	9.2	0.5	8.5	0.4	8.6	0.3	9.4	0.3	
Potassium, mEq/l	5.2	0.2	4.8	0.3	4.9	0.2	5.2	0.4	
Sodium, mEq/l	144	1	141	1	142	1	142	1	
Total Protein, g/dl	5.8	0.2	5.9	0.2	5.8	0.3	5.9	0.2	
Triglycerides, mg/dl	53	16	53	15	72	26	60	27	
Urea Nitrogen, mg/dl	12	2	13	2	12	1	13	3	
Study Identification	**Study E**		**Study F**		**Study G**		**Study H**		
Study Start Date	**Feb-97**		**Jun-97**		**Oct-97**		**Jul-98**		
Number of Animals	**15**		**15**		**15**		**15**		
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	
A/G Ratio	1.4	0.1	1.3	0.1	1.4	0.1	104	0.1	
Albumin, g/dl	3.3	0.1	3.2	0.2	3.3	0.1	3.4	0.1	
Alkaline Phosphatase, u/l	224	53	248	68	261	52	213	39	
ALT, u/l	27	4	28	3	29	5	32	5	
AST, u/l	109	18	114	14	104	17	108	25	
Calcium, mg/dl	10.1	0.2	9.6	0.2	9.5	0.2	9.4	0.2	
Chloride, mEq/l	105	1	104	1	102	1	100	2	
Cholesterol Total, mg/dl	62	8	56	11	63	11	69	8	
Creatinine, mg/dl	0.5	0.1	0.5	0	0.5	0	0.5	0	
Glucose, mg/dl	154	25	123	27	133	24	167	21	
Phosphorus, mg/dl	9.2	0.4	9.1	0.4	8.9	0.4	8.7	0.3	
Potassium, mEq/l	5.2	0.3	5	0.2	4.7	0.3	4.9	0.2	
Sodium, mEq/l	144	2	143	1	141	1	142	1	
Total Protein, g/dl	5.7	0.2	5.6	0.3	5.7	0.2	5.8	0.3	
Triglycerides, mg/dl	61	18	53	26	62	30	59	21	
Urea Nitrogen, mg/dl	11	2	11	2	12	3	11	1	

Table 8: Summary of Serum Chemistry Parameters from Individual Studies at 4 Weeks – Females

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**	
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
A/G Ratio	1.4	0.1	1.3	0.1	1.5	0.1	1.5	0.1
Albumin, g/dl	3.4	0.1	3.3	0.1	3.5	0.2	3.6	0.1
Alkaline Phosphatase, u/l	191	34	219	61	150	29	171	44
ALT, u/l	26	4	27	3	26	5	23	3
AST, u/l	91	17	102	14	108	21	101	19
Calcium, mg/dl	10.1	0.2	9.9	0.2	9.8	0.3	9.9	0.3
Chloride, mEq/l	106	1	105	1	107	1	107	1
Cholesterol Total, mg/dl	80	16	86	9	92	12	73	18
Creatinine, mg/dl	0.6	0	0.6	0.1	0.6	0	0.5	0.1
Glucose, mg/dl	158	28	161	12	179	23	155	33
Phosphorus, mg/dl	7.6	0.3	7.6	0.5	7.4	0.6	7.6	0.5
Potassium, mEq/l	4.6	0.3	4.7	0.3	4.8	0.3	4.6	0.3
Sodium, mEq/l	143	1	142	1	143	1	140	1
Total Protein, g/dl	5.8	0.2	5.7	0.2	5.8	0.2	6	0.2
Triglycerides, mg/dl	66	32	60	30	55	21	58	36
Urea Nitrogen, mg/dl	11	2	10	2	11	1	13	2
Study Identification	**Study E**		**Study F**		**Study G**		**Study H**	
Study Start Date	**Feb-97**		**Jun-97**		**Oct-97**		**Jul-98**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
A/G Ratio	1.4	0.1	1.5	0.1	1.4	0.1	1.6	0.1
Albumin, g/dl	3.6	0.2	3.5	0.2	3.4	0.1	3.7	0.1
Alkaline Phosphatase, u/l	142	36	137	32	161	47	142	21
ALT, u/l	24	4	24	4	28	6	24	3
AST, u/l	95	19	89	12	109	28	89	17
Calcium, mg/dl	10	0.3	9.9	0.3	9.9	0.2	9.4	0.2
Chloride, mEq/l	107	2	104	1	108	1	104	1
Cholesterol Total, mg/dl	89	13	75	15	80	12	76	9
Creatinine, mg/dl	0.6	0	0.6	0.1	0.5	0.1	0.5	0
Glucose, mg/dl	156	22	140	27	145	28	158	21
Phosphorus, mg/dl	8.2	0.5	8.1	0.5	7.4	0.6	6.7	0.4
Potassium, mEq/l	4.7	0.4	4.6	0.2	4.6	0.3	4.3	0.3
Sodium, mEq/l	142	1	141	1	142	2	142	1
Total Protein, g/dl	6.1	0.2	5.8	0.3	5.8	0.3	6	0.2
Triglycerides, mg/dl	55	13	56	14	57	22	41	12
Urea Nitrogen, mg/dl	12	2	12	2	12	2	12	2

Table 9: Summary of Serum Chemistry Parameters from Individual Studies at 8 Weeks – Males

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**	
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
A/G Ratio	1.2	0.1	1.2	0.1	1.1	0.1	1.3	0.1
Albumin, g/dl	3.4	0.1	3.4	0.1	3.3	0.3	3.5	0.1
Alkaline Phosphatase, u/l	177	51	160	33	150	38	147	29
ALT, u/l	36	4	33	5	40	12	31	6
AST, u/l	107	22	109	24	104	20	114	27
Calcium, mg/dl	10	0.3	9.4	0.3	10	0.3	9.8	0.2
Chloride, mEq/l	102	1	104	1	105	1	104	1
Cholesterol Total, mg/dl	58	11	61	11	69	13	54	5
Creatinine, mg/dl	0.5	0.1	0.6	0.1	0.5	0.1	0.6	0
Glucose, mg/dl	155	23	140	15	176	23	153	18
Phosphorus, mg/dl	7.5	0.5	7.3	0.5	7.6	0.6	8.2	0.5
Potassium, mEq/l	4.7	0.2	4.9	0.3	5	0.3	5.1	0.2
Sodium, mEq/l	142	1	143	1	145	1	143	1
Total Protein, g/dl	6.2	0.3	6.1	0.2	6.2	0.4	6.1	0.2
Triglycerides, mg/dl	66	17	67	20	99	49	80	36
Urea Nitrogen, mg/dl	13	3	13	1	15	3	15	3
Study Identification	**Study E**		**Study F**		**Study G**		**Study H**	
Study Start Date	**Feb-97**		**Jun-97**		**Oct-97**		**Jul-98**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
A/G Ratio	1.2	0.1	1.3	0.1	1.2	0.1	1.3	0.1
Albumin, g/dl	3.4	0.1	3.3	0.2	3.3	0.1	3.4	0.1
Alkaline Phosphatase, u/l	151	42	158	35	163	22	136	21
ALT, u/l	33	5	28	4	35	5	35	6
AST, u/l	111	19	91	16	100	19	89	14
Calcium, mg/dl	10	0.3	9.9	0.2	9.7	0.2	9.7	0.2
Chloride, mEq/l	105	2	105	2	105	1	104	1
Cholesterol Total, mg/dl	61	7	55	9	59	9	65	7
Creatinine, mg/dl	0.5	0	0.5	0.1	0.5	0.1	0.6	0
Glucose, mg/dl	154	17	150	21	141	18	169	14
Phosphorus, mg/dl	8.1	0.6	7.8	0.4	7.8	0.4	7.7	0.4
Potassium, mEq/l	5	0.3	4.9	0.3	4.9	0.3	4.9	0.2
Sodium, mEq/l	141	1	142	1	143	1	144	1
Total Protein, g/dl	6.2	0.3	5.9	0.3	6	0.2	6	0.2
Triglycerides, mg/dl	83	36	65	24	61	34	74	25
Urea Nitrogen, mg/dl	16	2	16	2	14	3	13	2

Table 10: Summary of Serum Chemistry Parameters from Individual Studies at 8 Weeks – Females

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**	
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
A/G Ratio	1.3	0.1	1.3	0.1	1.3	0.1	1.5	0.1
Albumin, g/dl	3.5	0.2	3.5	0.1	3.5	0.2	3.7	0.2
Alkaline Phosphatase, u/l	147	26	142	46	98	25	129	44
ALT, u/l	29	7	28	4	29	4	28	4
AST, u/l	87	14	110	18	92	20	123	26
Calcium, mg/dl	10	0.2	9.5	0.2	9.8	0.4	9.8	0.3
Chloride, mEq/l	106	1	105	1	106	1	106	1
Cholesterol Total, mg/dl	76	15	70	8	87	14	67	15
Creatinine, mg/dl	0.6	0	0.6	0.1	0.6	0.1	0.6	0
Glucose, mg/dl	179	18	185	24	181	29	149	30
Phosphorus, mg/dl	6.4	0.6	6.4	0.6	6.2	0.9	6.6	0.7
Potassium, mEq/l	4.2	0.3	4.6	0.3	4.5	0.3	4.5	0.2
Sodium, mEq/l	141	1	142	1	142	1	142	1
Total Protein, g/dl	6.2	0.3	6.2	0.3	6.2	0.4	6.4	0.3
Triglycerides, mg/dl	69	24	61	22	64	36	63	26
Urea Nitrogen, mg/dl	12	2	11	2	14	2	13	2
Study Identification	**Study E**		**Study F**		**Study G**		**Study H**	
Study Start Date	**Feb-97**		**Jun-97**		**Oct-97**		**Jul-98**	
Number of Animals	**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
A/G Ratio	1.3	0.1	1.4	0.1	1.3	0.1	1.7	0.1
Albumin, g/dl	3.7	0.2	3.6	0.2	3.6	0.2	3.8	0.2
Alkaline Phosphatase, u/l	93	21	94	23	113	41	90	14
ALT, u/l	25	3	31	5	30	5	25	3
AST, u/l	101	17	89	17	97	19	85	11
Calcium, mg/dl	10	0.2	10.1	0.4	9.8	0.3	9.8	0.3
Chloride, mEq/l	107	2	107	1	106	1	104	1
Cholesterol Total, mg/dl	81	10	77	13	74	11	70	7
Creatinine, mg/dl	0.6	0	0.6	0	0.5	0	0.6	0
Glucose, mg/dl	167	29	177	24	170	32	169	24
Phosphorus, mg/dl	6.7	0.7	6.5	0.6	6.2	0.5	6.4	0.6
Potassium, mEq/l	4.7	0.3	4.5	0.4	4.5	0.3	4.4	0.2
Sodium, mEq/l	141	1	142	1	142	1	143	1
Total Protein, g/dl	6.4	0.3	6.2	0.3	6.3	0.4	6.1	0.3
Triglycerides, mg/dl	74	33	56	15	64	25	53	14
Urea Nitrogen, mg/dl	14	2	14	2	13	1	13	2

Table 11: Summary of Serum Chemistry Parameters from Individual Studies at 12 Weeks – Males

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**		**Study E**	
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**		**Feb-97**	
Number of Animals	**15**		**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
A/G Ratio	1.1	0.1	1.1	0.1	1.1	0.1	1.3	0.1	1.2	0.1
Albumin, g/dl	3.4	0.1	3.4	0.1	3.3	0.2	3.5	0.1	3.4	0.1
Alkaline Phosphatase, u/l	146	46	125	32	118	25	104	22	121	31
ALT, u/l	31	4	32	5	31	5	27	5	35	5
AST, u/l	77	9	90	14	91	15	110	32	103	17
Calcium, mg/dl	10	0.3	9.9	0.3	10.1	0.2	9.6	0.3	9.7	0.2
Chloride, mEq/l	103	2	105	1	105	1	105	1	104	2
Cholesterol Total, mg/dl	57	11	59	11	61	12	57	8	59	9
Creatinine, mg/dl	0.6	0	0.6	0	0.6	0	0.6	0	0.6	0.1
Glucose, mg/dl	197	22	156	19	167	26	154	17	173	20
Phosphorus, mg/dl	7.2	0.5	7	0.5	7.2	0.4	7.3	0.4	7	0.6
Potassium, mEq/l	4.6	0.3	4.7	0.3	5	0.2	5.1	0.4	5	0.3
Sodium, mEq/l	141	1	143	1	142	1	143	1	142	2
Total Protein, g/dl	6.5	0.2	6.4	0.2	6.1	0.3	6.3	0.2	6.4	0.3
Triglycerides, mg/dl	62	21	75	32	90	33	64	13	75	22
Urea Nitrogen, mg/dl	12	2	13	2	13	2	14	3	15	2
Study Identification	**Study F**		**Study G**		**Study H**		**Study I**		**Study J**	
Study Start Date	**Jun-97**		**Oct-97**		**Jul-98**		**Mar-93**		**Mar-93**	
Number of Animals	**15**		**15**		**15**		**24**		**25**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
A/G Ratio	1.2	0.1	1.2	0.1	1.3	0.1	NA	NA	NA	NA
Albumin, g/dl	3.3	0.2	3.4	0.1	3.4	0.1	4.4	0.2	4.3	0.2
Alkaline Phosphatase, u/l	117	22	115	20	121	22	130	22	160	43
ALT, u/l	31	3	31	4	35	6	42	9	40	7
AST, u/l	92	20	88	17	92	18	80	15	81	21
Calcium, mg/dl	9.9	0.2	9.8	0.2	9.9	0.2	10.7	0.6	10.6	0.4
Chloride, mEq/l	107	2	104	1	102	1	102	3	101	3
Cholesterol Total, mg/dl	55	11	62	12	61	6	88	17	71	12
Creatinine, mg/dl	0.6	0	0.6	0	0.6	0	0.4	0	0.4	0
Glucose, mg/dl	175	23	159	29	174	18	147	41	143	30
Phosphorus, mg/dl	7.2	0.6	7.2	0.6	7.1	0.5	9.5	1.3	9	1.1
Potassium, mEq/l	5	0.2	4.8	0.3	4.8	0.2	6	0.6	5.9	0.6
Sodium, mEq/l	143	1	141	1	142	1	149	2	149	2
Total Protein, g/dl	6.1	0.3	6.2	0.2	6.0	0.2	6.7	0.3	6.7	0.3
Triglycerides, mg/dl	72	26	79	46	66	20	92	42	73	21
Urea Nitrogen, mg/dl	15	1	14	3	13	2	10	2	13	2

Table 12: Summary of Serum Chemistry Parameters from Individual Studies at 12 Weeks – Females

Study Identification	**Study A**		**Study B**		**Study C**		**Study D**		**Study E**	
Study Start Date	**Oct-96**		**May-97**		**Apr-97**		**Nov-96**		**Feb-97**	
Number of Animals	**15**		**15**		**15**		**15**		**15**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
A/G Ratio	1.3	0.1	1.1	0.1	1.3	0.1	1.3	0.1	1.3	0.1
Albumin, g/dl	3.8	0.2	3.5	0.1	3.7	0.2	3.5	0.2	3.7	0.3
Alkaline Phosphatase, u/l	97	21	117	44	72	17	97	28	68	25
ALT, u/l	34	25	27	5	26	4	30	6	28	4
AST, u/l	83	26	102	17	95	13	116	33	97	14
Calcium, mg/dl	10.3	0.3	10	0.2	9.8	0.3	9.6	0.4	9.8	0.2
Chloride, mEq/l	107	2	107	2	105	2	105	2	105	1
Cholesterol Total, mg/dl	71	14	72	8	79	13	66	16	72	11
Creatinine, mg/dl	0.6	0.1	0.6	0	0.6	0	0.6	0	0.6	0.1
Glucose, mg/dl	186	18	177	16	171	19	183	27	154	23
Phosphorus, mg/dl	6.3	0.5	5.9	0.6	6	0.6	5.8	0.6	5.6	0.6
Potassium, mEq/l	4.3	0.3	4.5	0.3	4.4	0.3	4.5	0.3	4.3	0.1
Sodium, mEq/l	142	2	141	1	142	1	141	2	143	1
Total Protein, g/dl	6.6	0.3	6.5	0.3	6.5	0.4	6.3	0.4	6.4	0.4
Triglycerides, mg/dl	51	13	75	27	59	16	64	32	62	24
Urea Nitrogen, mg/dl	12	2	11	2	13	2	12	2	13	2

Study Identification	**Study F**		**Study G**		**Study H**		**Study I**		**Study J**	
Study Start Date	**Jun-97**		**Oct-97**		**Jul-98**		**Mar-93**		**Mar-93**	
Number of Animals	**15**		**15**		**15**		**24**		**24**	
	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.	Mean	+/- S.D.
A/G Ratio	1.3	0.1	1.3	0.1	1.5	0.1	NA	NA	NA	NA
Albumin, g/dl	3.7	0.3	3.7	0.2	3.9	0.2	5.2	0.6	4.9	0.5
Alkaline Phosphatase, u/l	65	17	79	38	76	26	78	23	87	31
ALT, u/l	33	6	25	7	26	3	37	10	39	9
AST, u/l	106	18	94	24	84	14	72	13	76	19
Calcium, mg/dl	10.1	0.4	9.8	0.3	9.9	0.2	10.9	0.4	10.8	0.5
Chloride, mEq/l	107	1	108	2	103	1	101	4	101	3
Cholesterol Total, mg/dl	73	20	74	14	72	9	97	22	85	16
Creatinine, mg/dl	0.6	0.1	0.6	0.1	0.6	0.1	0.4	0.1	0.4	0.1
Glucose, mg/dl	170	11	181	35	169	13	140	31	141	28
Phosphorus, mg/dl	6.1	0.7	6	0.5	5.6	0.6	8.6	1.3	8.2	1.2
Potassium, mEq/l	4.4	0.3	4.4	0.3	4.4	0.2	5.9	0.5	5.7	0.5
Sodium, mEq/l	142	2	141	2	141	1	146	2	146	2
Total Protein, g/dl	6.5	0.5	6.5	0.4	6.5	0.3	7.3	0.6	7	0.4
Triglycerides, mg/dl	61	28	64	29	53	28	68	31	67	19
Urea Nitrogen, mg/dl	13	2	14	2	13	2	12	2	13	3

Figure 1: Leukocytes (Males)

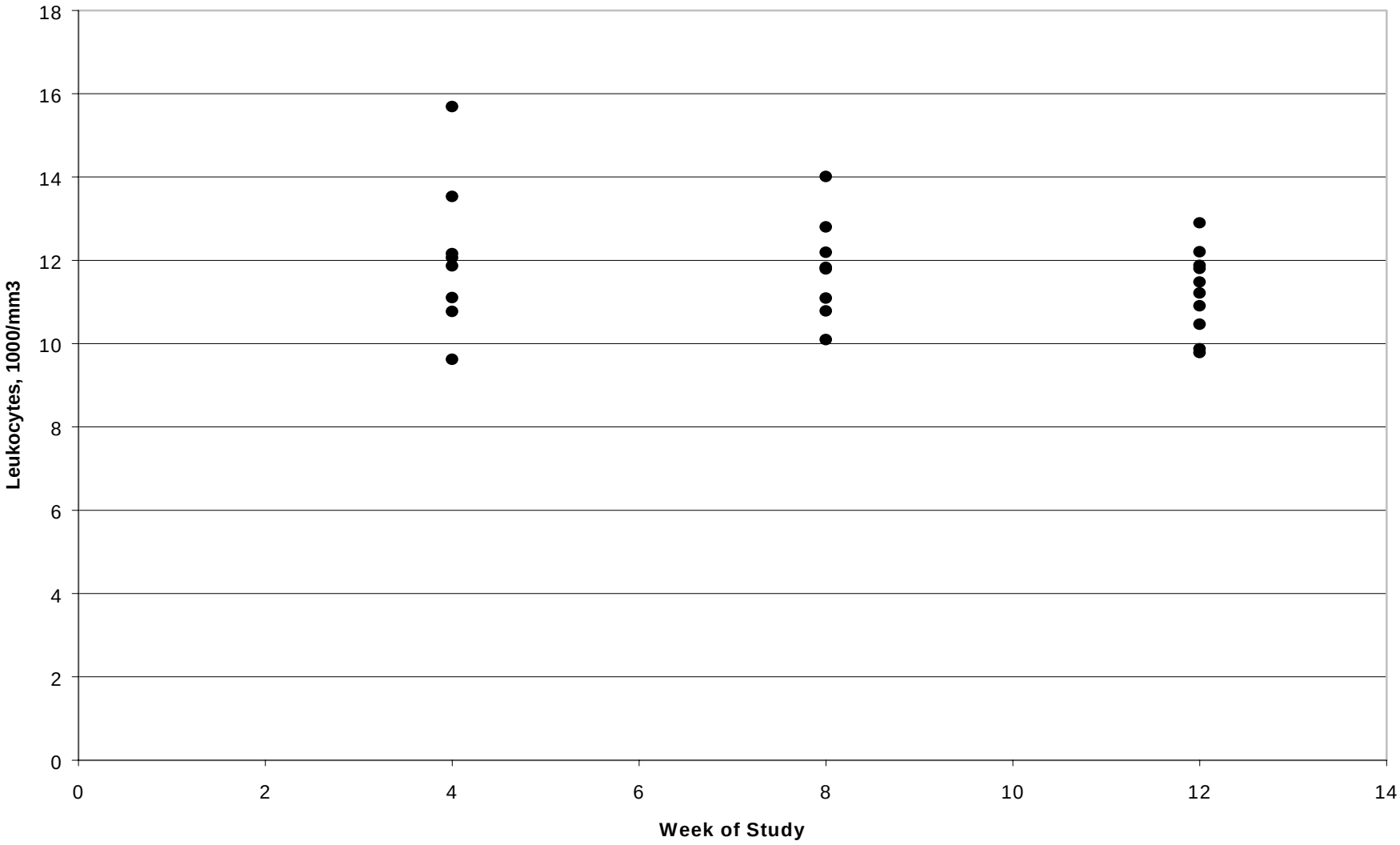

Figure 2: Leukocytes (Females)

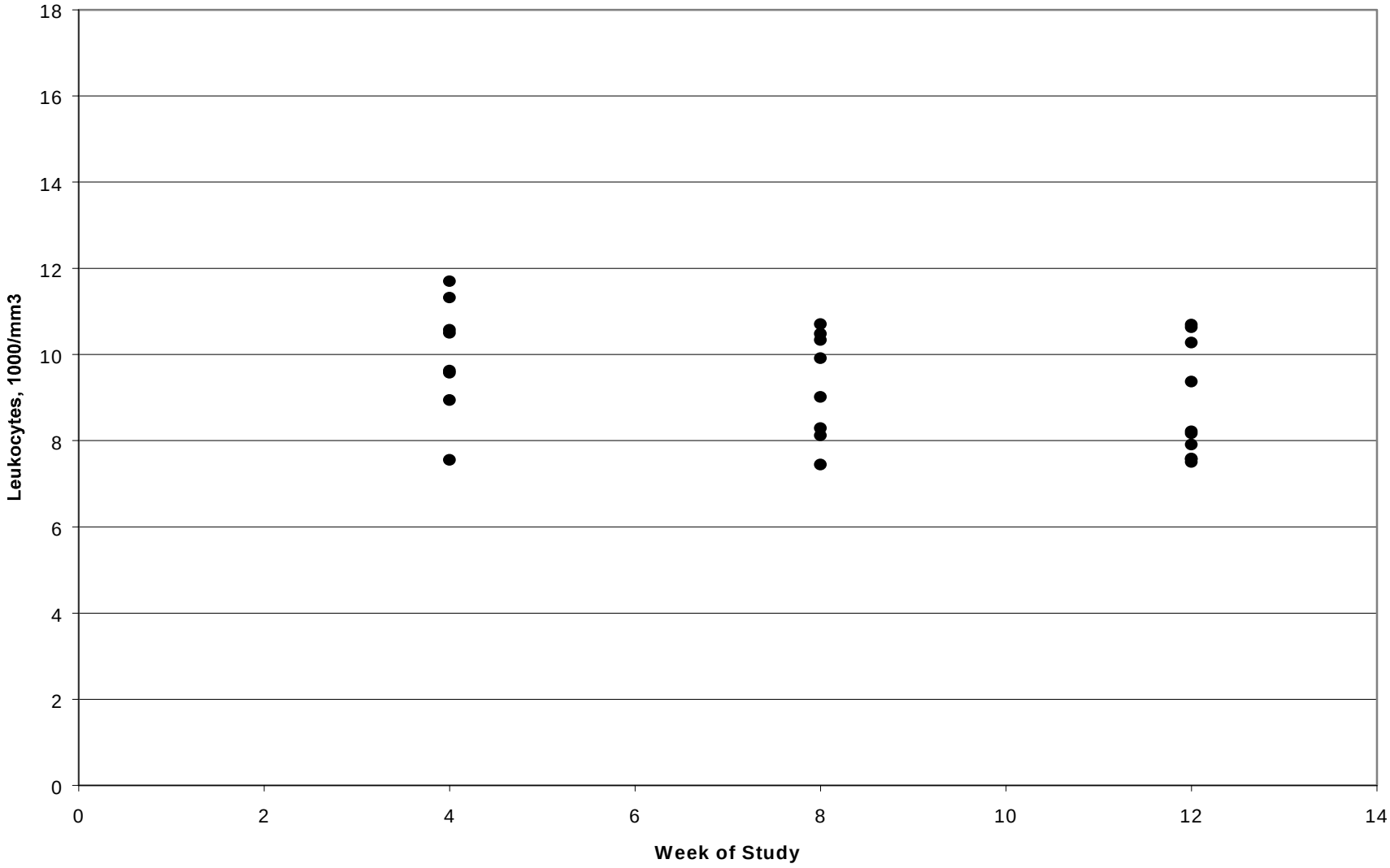

Figure 3: Lymphocytes (Males)

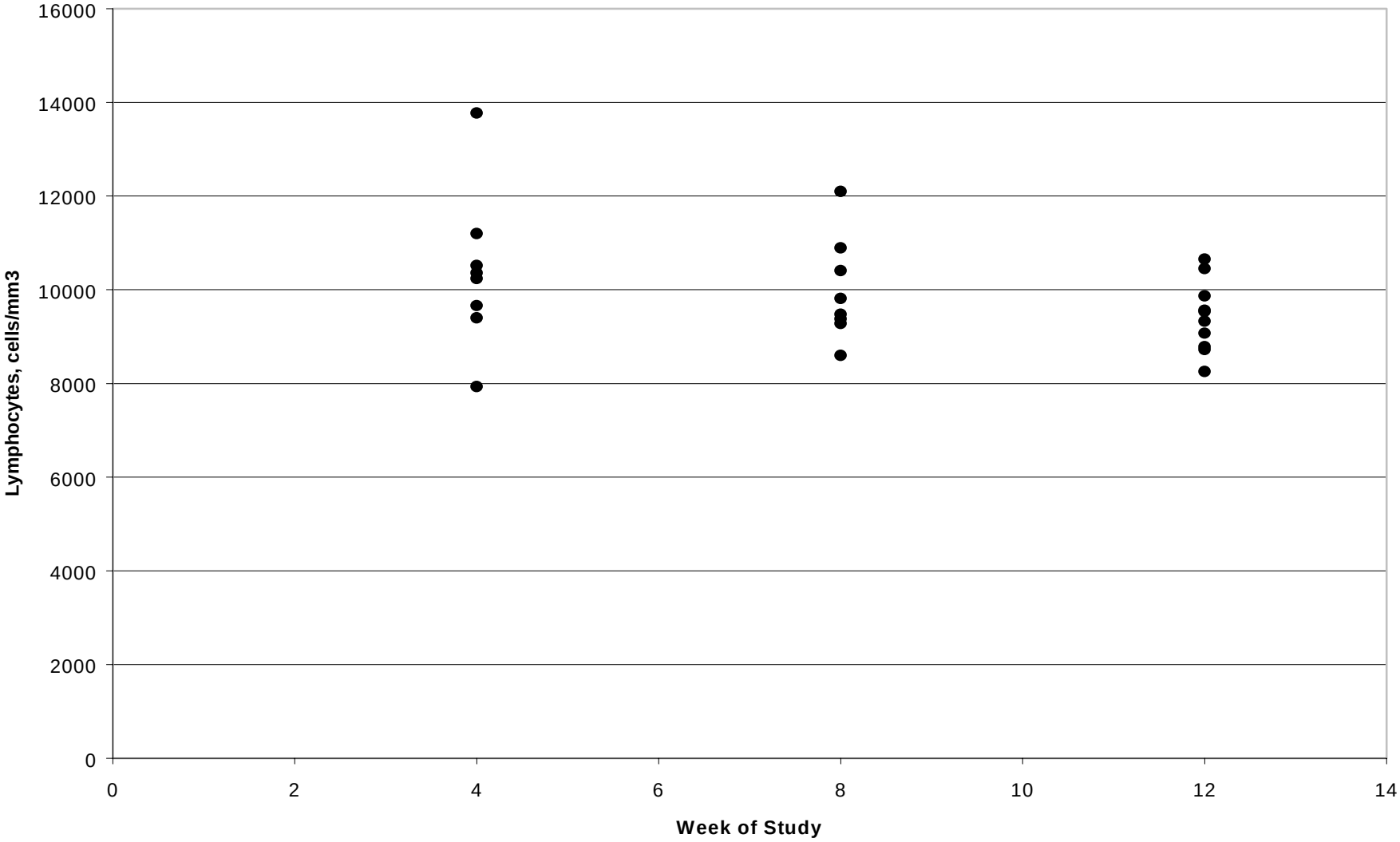

Figure 4: Lymphocytes (Females)

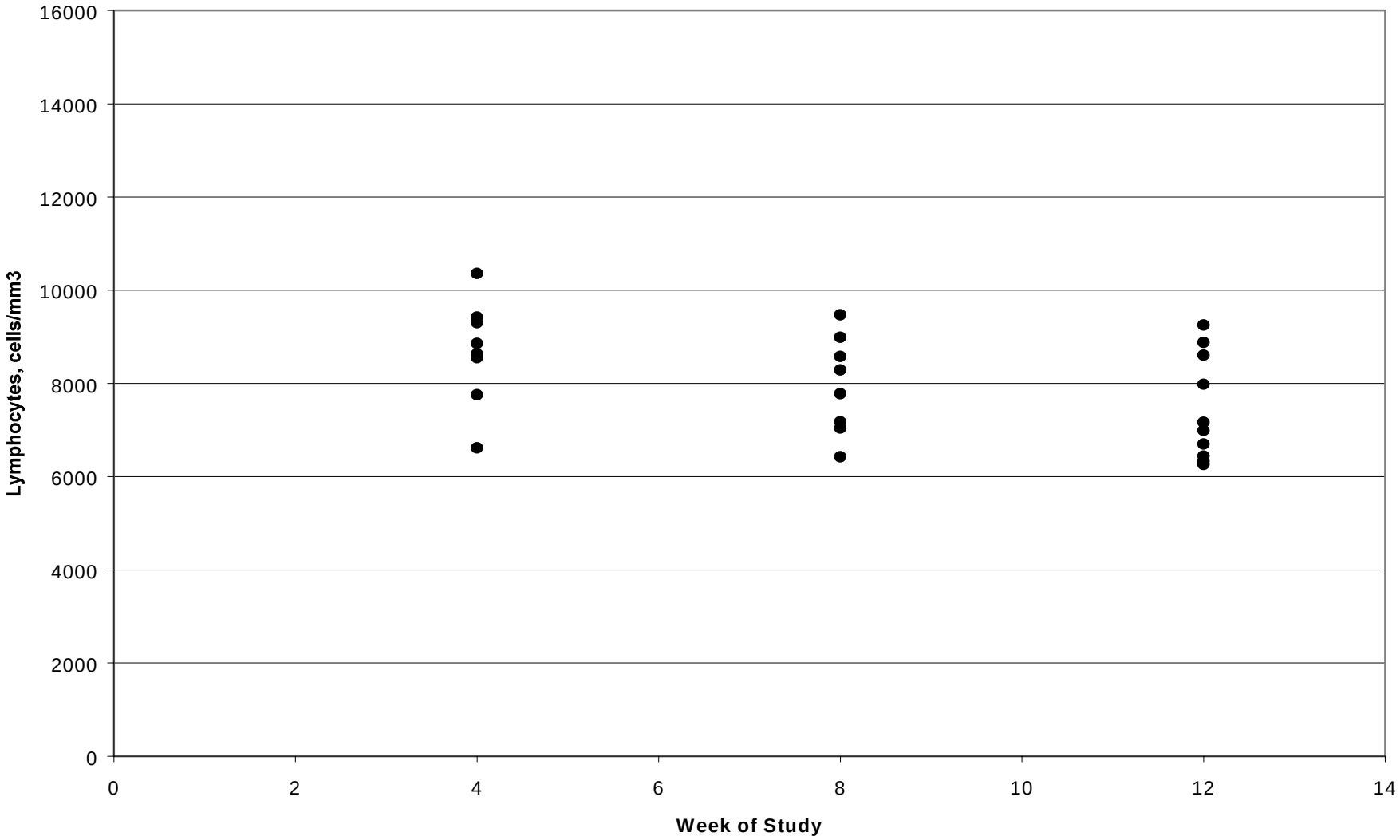

Figure 5: Alanine Aminotransferase (Males)

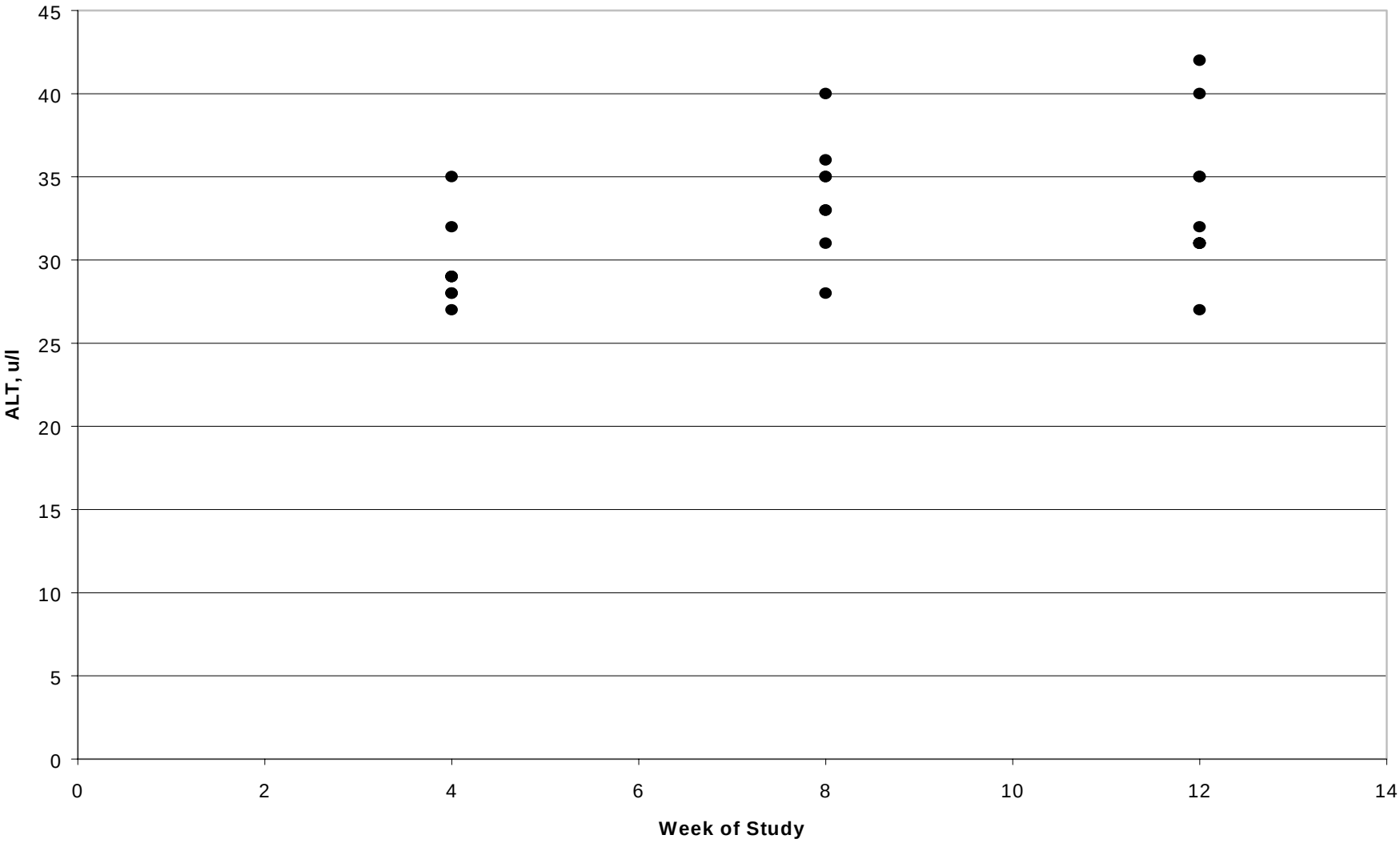

Figure 6: Alanine Aminotransferase (Females)

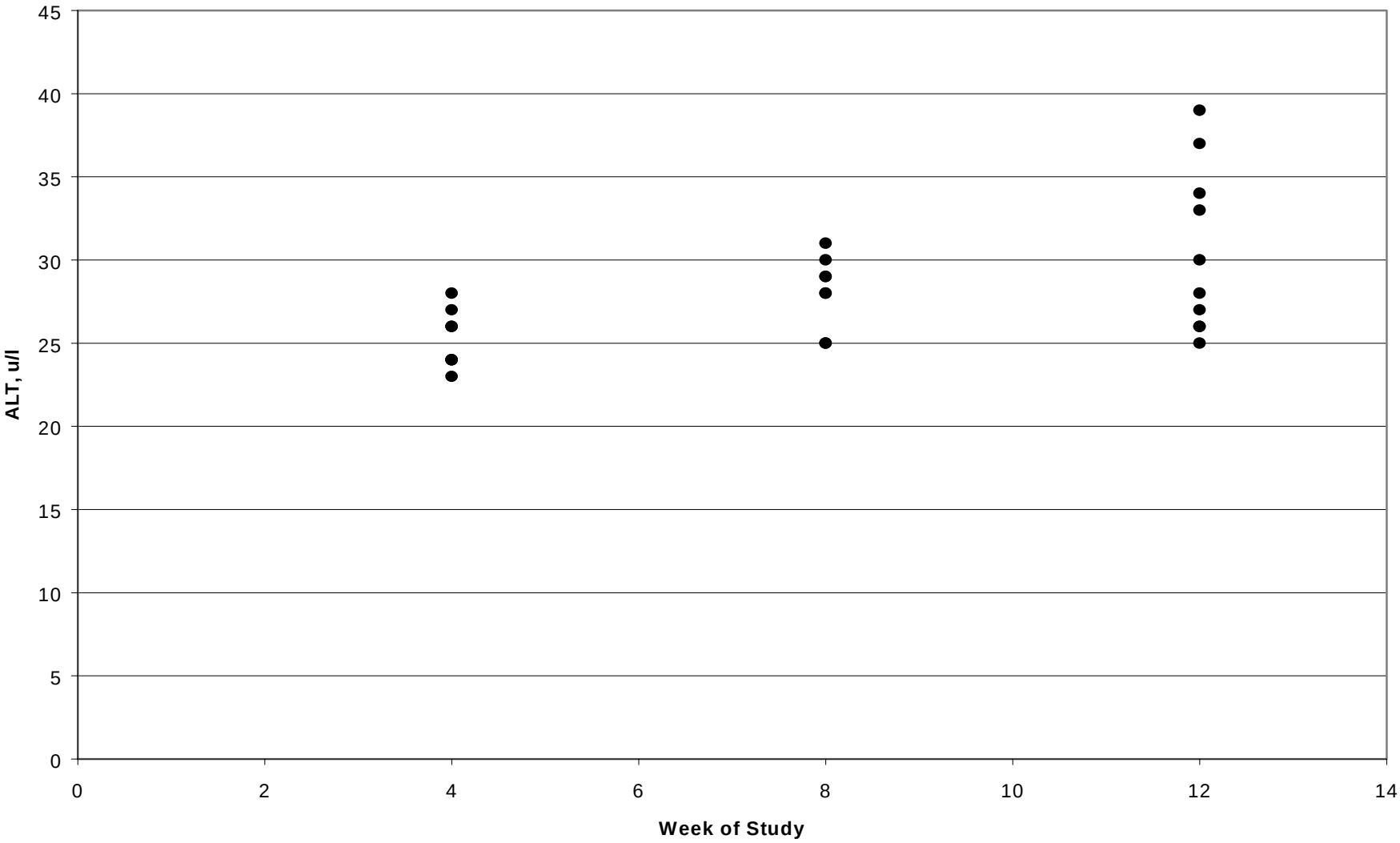

Figure 7: Aspartate Aminotransferase (Males)

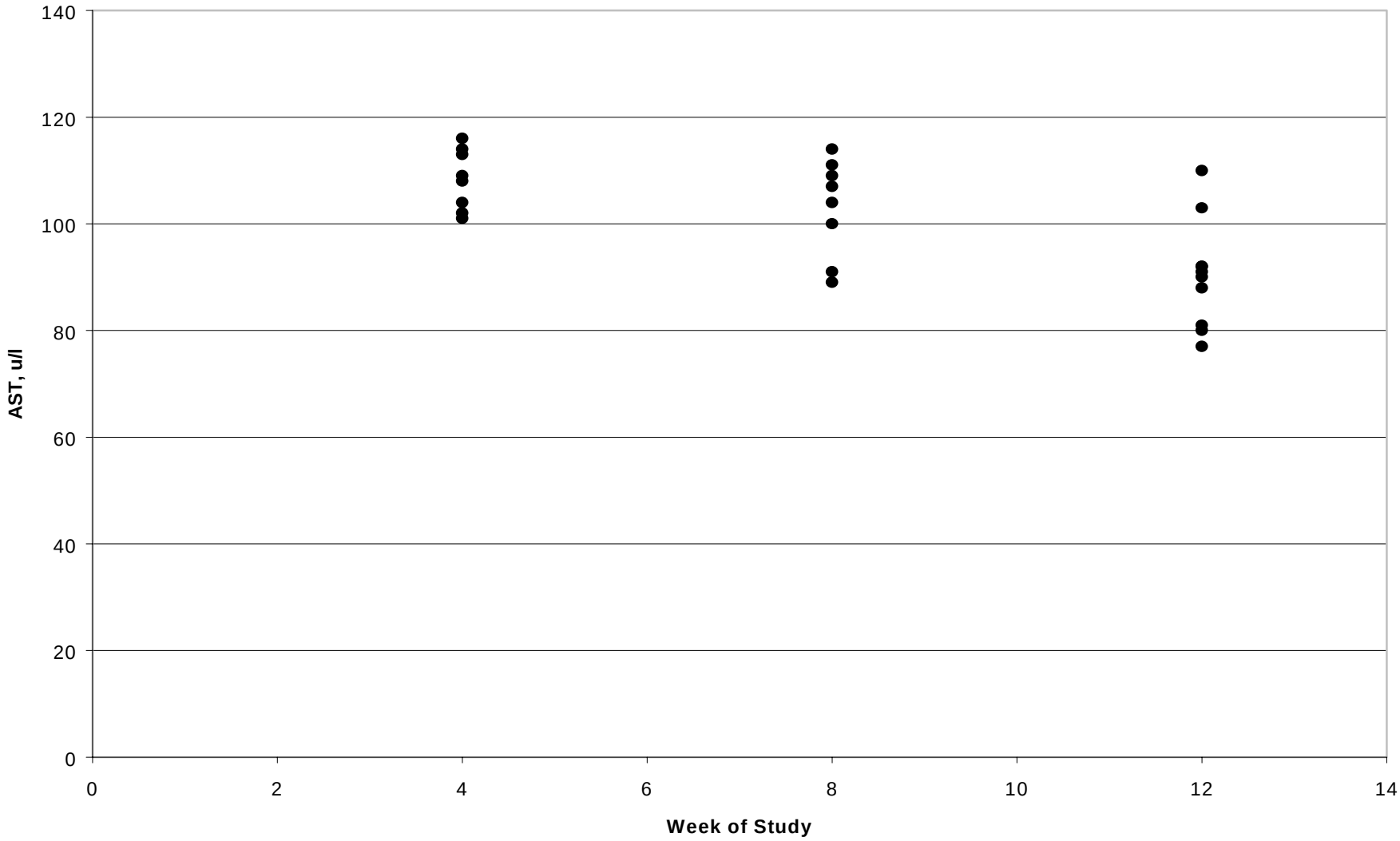

Figure 8: Aspartate Aminotransferase (Females)

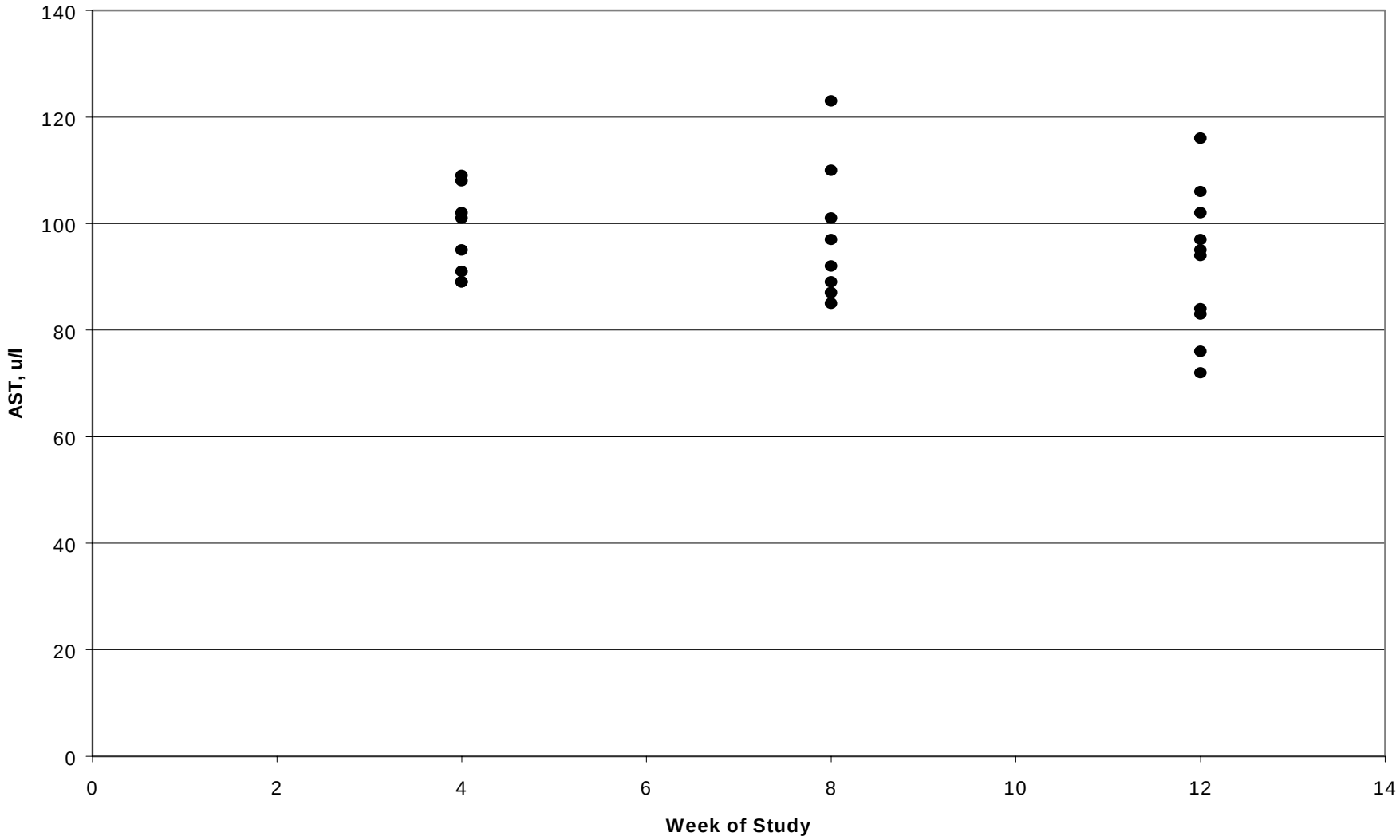

Figure 9: Cholesterol Total (Males)

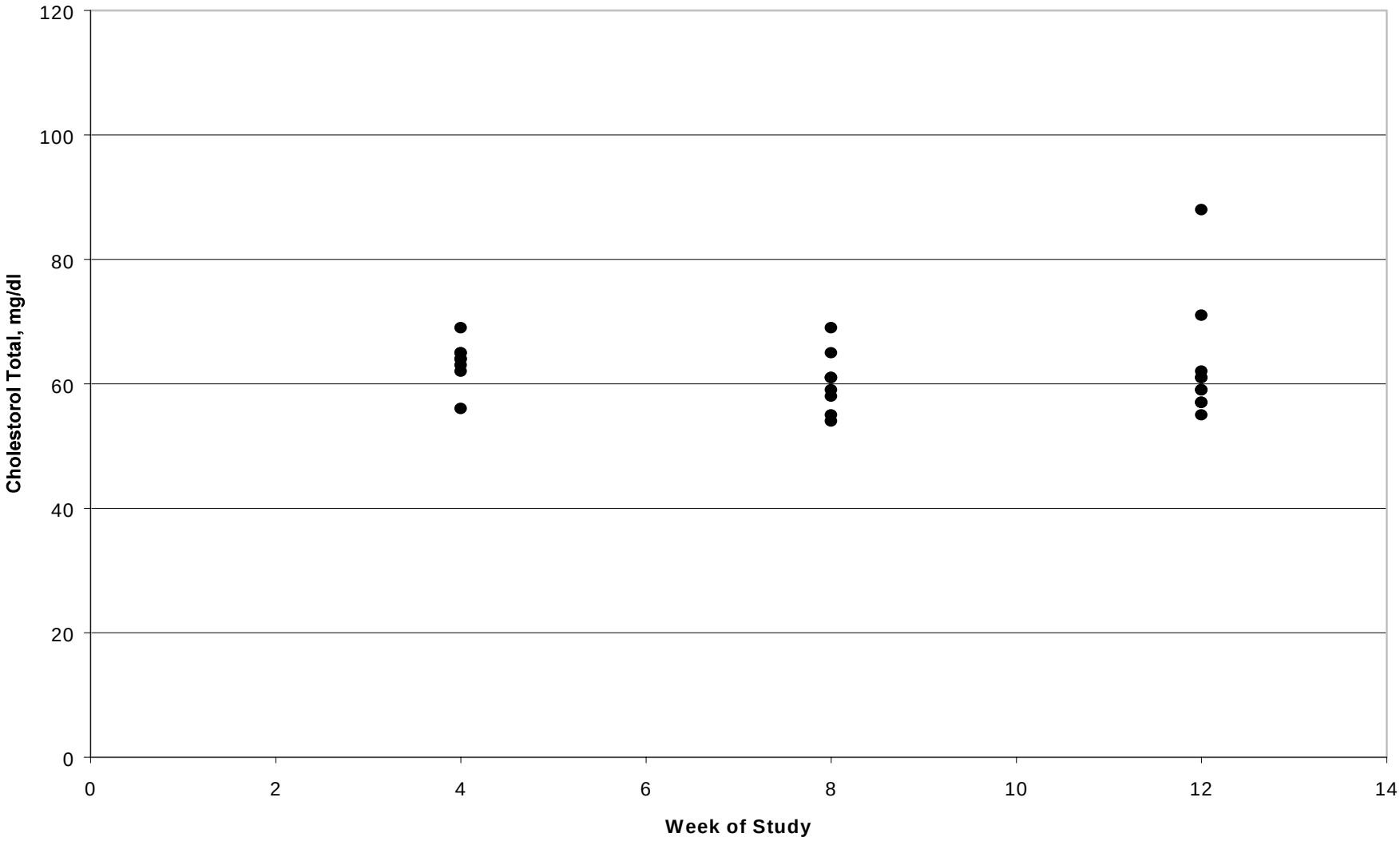

Figure 10: Cholesterol Total (Females)

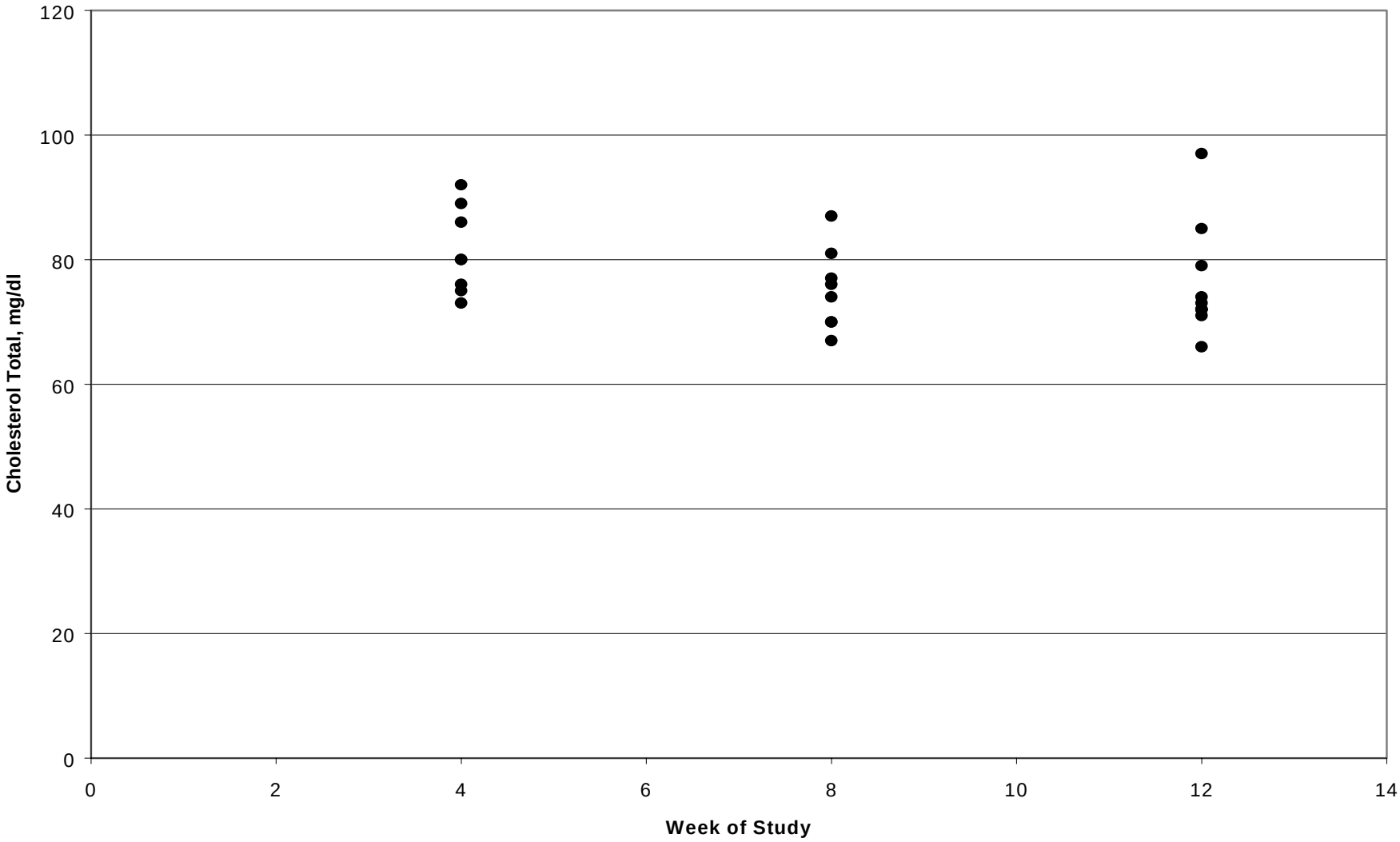

Figure 11: Glucose (Males)

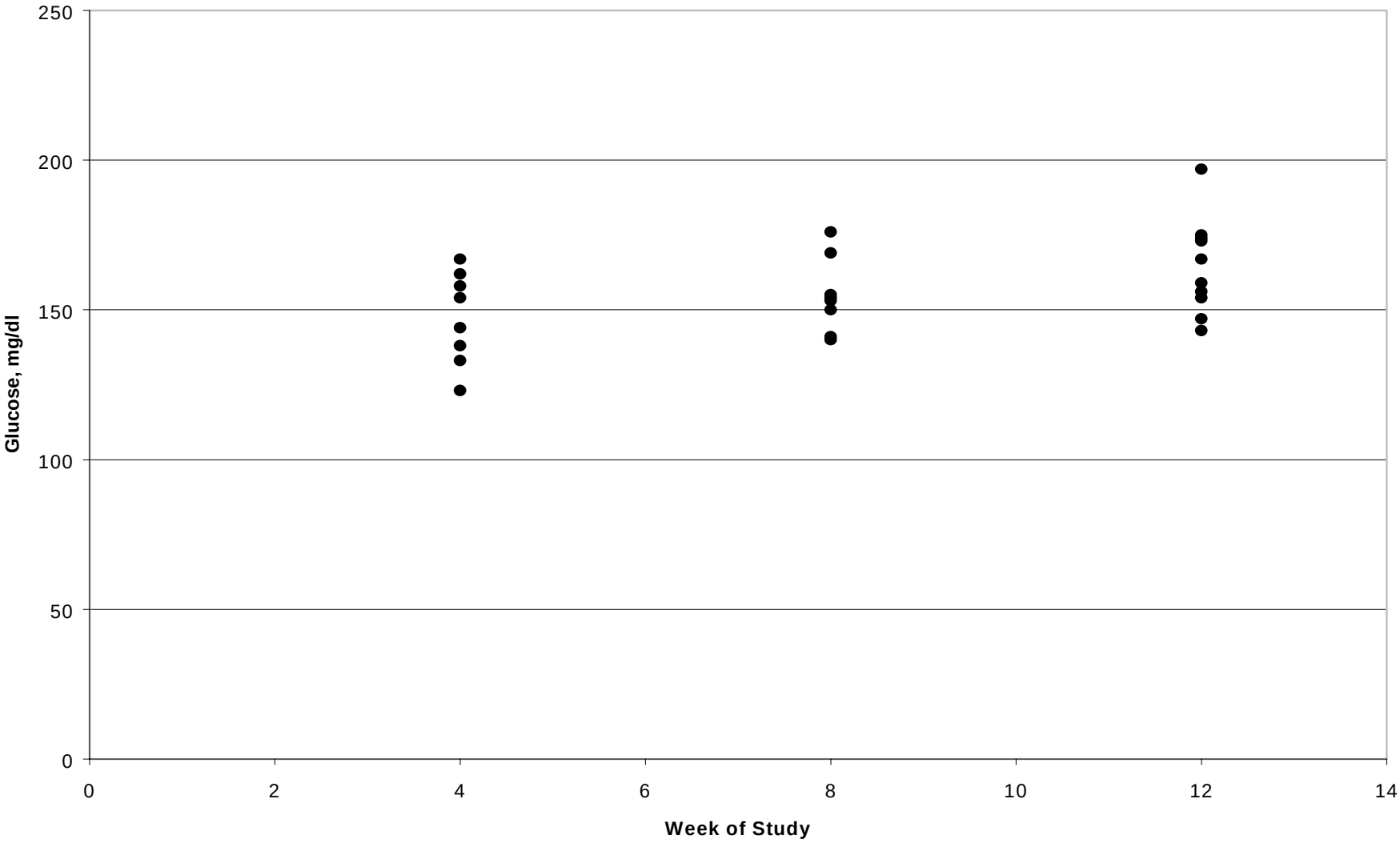

Figure 12: Glucose (Females)

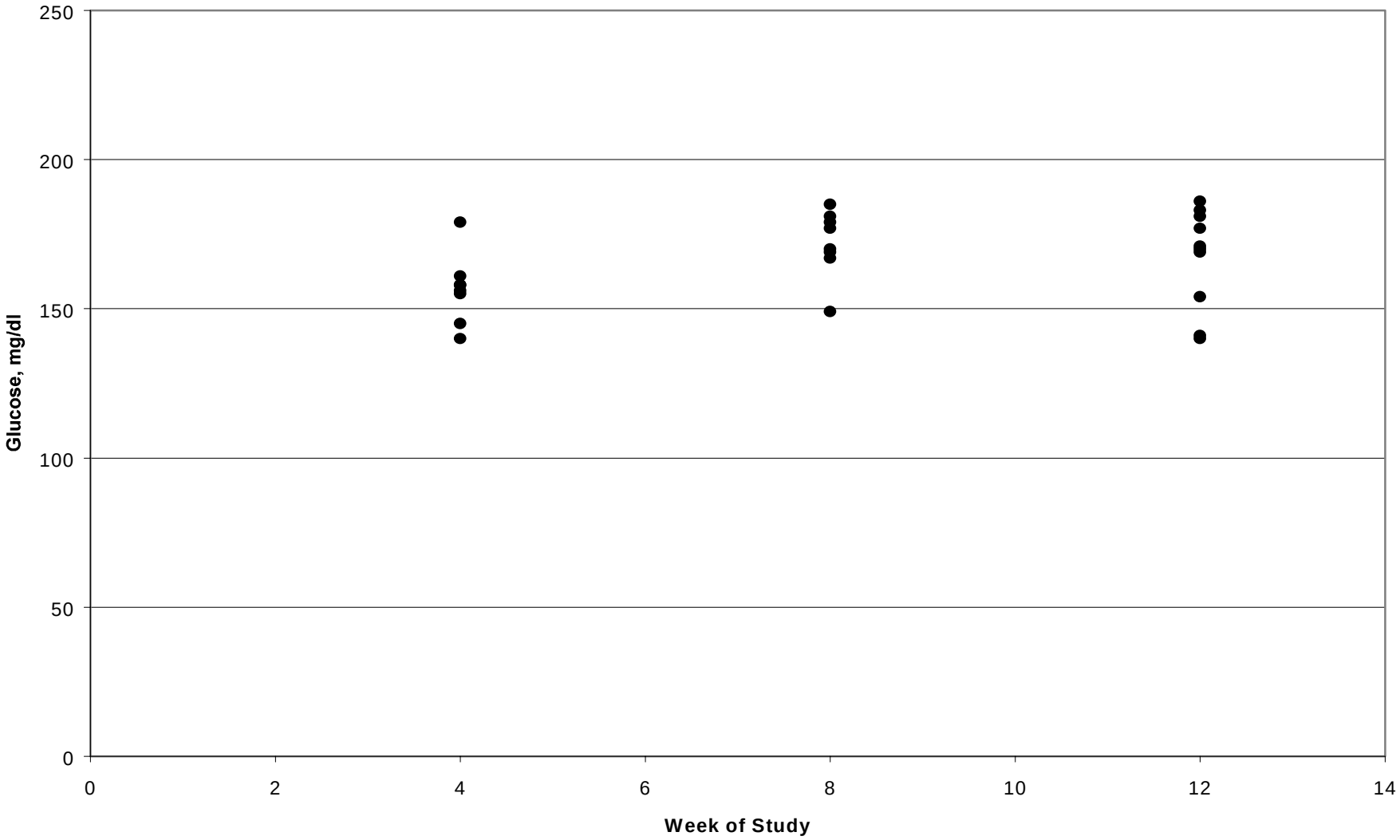

Figure 13: Triglycerides (Males)

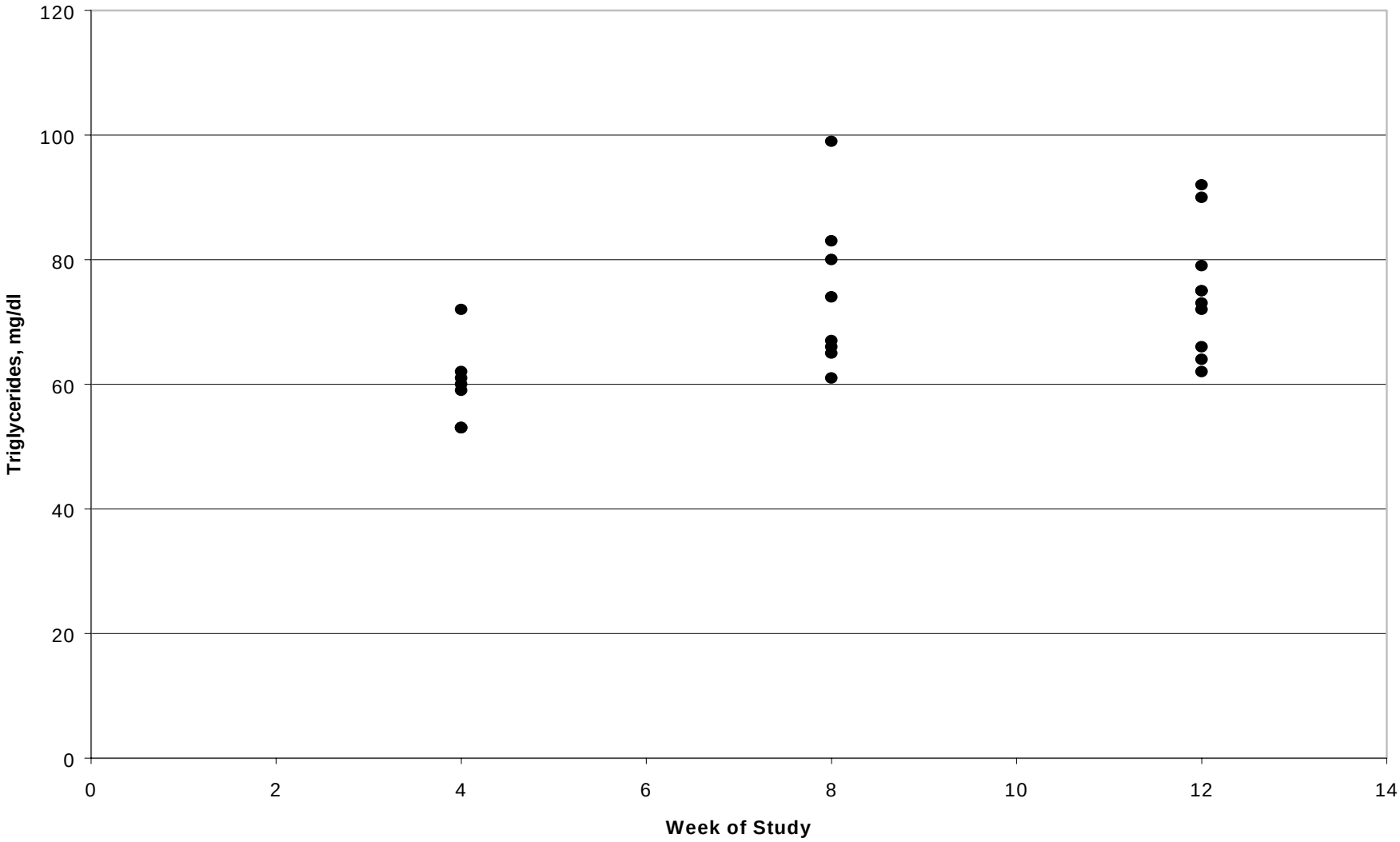

Figure 14: Triglycerides (Females)