

Clinical Laboratory Parameters for Crl:WI(Han)

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INTRODUCTION	2
PURPOSE	2
COMMON STUDY PARAMETERS	2
DATA PRESENTED	3
NOTES AND ABBREVIATIONS	3
ACKNOWLEDGMENTS	4
REFERENCES	4
REQUEST FOR DATA	4
Table 1: Coagulation Data: Rats 8-16 Weeks Old - Males	5
Table 2: Coagulation Data: Rats 8-16 Weeks Old - Females	5
Table 3: Hematology Data: Rats 8-16 Weeks Old - Males	6
Table 4: Hematology Data: Rats 8-16 Weeks Old - Females	7
Table 5: Serum Chemistry Data: Rats 8-16 Weeks Old - Males	8
Table 6: Serum Chemistry Data: Rats 8-16 Weeks Old - Females	9
Table 7: Coagulation Data: Rats 17 Weeks of Age or Greater - Males	10
Table 8: Coagulation Data: Rats 17 Weeks of Age or Greater - Females	10
Table 9: Hematology Data: Rats 17 Weeks of Age or Greater - Males	11
Table 10: Hematology Data: Rats 17 Weeks of Age or Greater - Females	12
Table 11: Serum Chemistry Data: Rats 17 Weeks of Age or Greater - Males	13
Table 12: Serum Chemistry Data: Rats 17 Weeks of Age or Greater - Females	14

INTRODUCTION

A range of normal or expected values for coagulation, hematology and serum chemistry can be a useful tool for interpreting toxicology and safety studies. However, such information is often difficult to find. Although control group data are included along with test data when reporting findings in the literature they are rarely published alone and almost never as the primary topic of the paper and therefore not referenced by a keyword. For this reason, control data are often overlooked in computerized searches (1). Furthermore, laboratories that conduct a small number of studies or are considering switching test strains may not have access to ample amounts of in-house control data. To this end, we have compiled clinical laboratory data from approximately 30 studies conducted in the CrI:WI(Han) rat. It is our hope that you, the reader, will find this information useful.

PURPOSE

The purpose of this publication is to provide the reviewing toxicologist or clinical pathologist with a range of normal or expected values for selected coagulation, hematology and serum chemistry parameters obtained at various intervals from control animals of approximately 30 preclinical safety studies. It is recognized that different analytical methods as well as environmental and technique related variables influence the values obtained for a particular parameter (1-3). As the data in this publication were obtained from a single testing facility and from animals from a single production site many of these variables have been eliminated or minimized. The data included in this publication are for informational purposes only and are not intended for conclusive interpretation of any toxicological findings. There is general agreement among clinical pathologists and toxicologists that concurrent control data for a parameter in question are best for comparison and for determining a potential test article related finding (4-8). In fact, the Joint Scientific Committee for International Harmonization of Clinical Pathology Testing has gone as far as to state "The concurrent control data are more appropriate than historical reference ranges for comparison with test material groups" (4,9). However, there are instances when historical control data have value (6-9). This information may be helpful in explaining why a particular statistically significant study finding is not of biological or toxicological significance. Historical control data can also help to explain the severity of a particular finding. It can help put that finding into perspective. Historical control data can also help detect population drift or analytical problems within a laboratory (5).

COMMON STUDY PARAMETERS

The approximately 30 studies included in this publication were conducted between 2002 and 2007 at Charles River Laboratories Preclinical Services Montreal Inc. in Senneville, Quebec. The animals used in these studies were all CrI:WI(Han) rats from the Charles River Laboratories production site located in Raleigh, NC. All studies were conducted in accordance with Good Laboratory Practice regulations of the US Food and Drug Administration or the Environmental Protection Agency and/or the Standard Operating Procedures of the laboratory. All studies were designed to support in-house research or marketing permits.

The data included in this publication were obtained from control group animals of various types of regulatory studies including dietary, oral gavage or intravenous injection studies. Rats included in this publication were housed singly or in pairs of the same sex in stainless steel wire mesh cages with free access to tap 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 the studies were conducted over a five-year period there were some variations 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 and integrity of the studies. All rats were fed Purina PMI Certified Rodent Chow 5002 or PMI Rodent 18% Chow #5LG3.

The clinical laboratory evaluations were performed at intervals specified in individual study protocols and are presented here by age of animal, less than 17 weeks of age or more than 17 weeks of age, at the time of evaluation. The rats were fasted overnight prior to blood collection. All blood was collected from the abdominal aorta. Hematology and clotting evaluations were performed with the aid of a Bayer ADVIA 120 analyzer and ACL-Advance instrument while a Hitachi P800 analyzer was used for serum chemistry determinations.

DATA PRESENTED

The blood clotting, hematology data and serum chemistry are separated by sex and age range at the time of evaluation.

NOTES AND ABBREVIATIONS

A/G Ratio = albumin/globulin ratio, a calculated parameter

Alanine Aminotransferase = ALT (aka SGPT)

Aspartate Aminotransferase = AST (aka SGOT)

CH = Red Cell Hemoglobin Content

CHCM = Corpuscular Hemoglobin Concentration Mean

HDW = Hemoglobin Concentration Distribution Width

Mean Corp Hgb Conc = Mean Corpuscular Hemoglobin Concentration

Mean Corp Hgb = Mean Corpuscular Hemoglobin

Mean Corp Vol = Mean Corpuscular Volume

N = number of animals included in determination

PDW = Platelet Distribution Width

Range = Minimum to maximum values obtained when N < 20; 2.5 - 97.5th percentile when N > 20

RDW = Red Cell Volume Distribution Width

S.D. = Standard Deviation

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REQUEST FOR DATA

The purpose of this and other publications by Charles River is to assist you, our clients, in evaluating your data. Our aim is to provide you with the data that you need to do your job well. We welcome your input and any suggestions you may have on ways to improve the usefulness of this document as well as topics for future documents. However, the publication is only as good as the data and the data usually improves in accuracy as the sample size increases. To this end we invite and encourage you to participate in our ongoing efforts to provide up to date information on historical control data on clinical laboratory determinations and on the incidence of neoplastic and non-neoplastic lesions in all strains of rats and mice supplied by Charles River. If you or someone in your laboratory is willing to participate, please contact Mary Giknis through Charles River, 251 Ballardvale Street, Wilmington, MA 01887, 781-222-6000 or at MLAGIKNIS@verizon.net.

Table 1: Coagulation Data: Rats 8-16 Weeks Old - Males

TEST	UNIT	N	MEAN	S.D	RANGE
Fibrinogen	mg/dL	71	158.4	24	109.7- 212.4
Prothrombin Time	sec	140	13.61	0.8	12.5- 15.7
Activated Partial Prothrombin Time	sec	139	21.6	4.12	14.3- 31.5

Table 2: Coagulation Data: Rats 8-16 Weeks Old - Females

TEST	UNIT	N	MEAN	S.D	RANGE
Fibrinogen	mg/dL	69	131.6	18.5	100.1-188.5
Prothrombin Time	sec	128	13.44	0.86	11.95-14.8
Activated Partial Prothrombin Time	sec	128	20.04	4.22	14-28.8

Table 3: Hematology Data: Rats 8-16 Weeks Old - Males

TEST	UNIT	N	MEAN	S.D.	RANGE
MPV	fL(μm^3)	181	7.7	0.8	6.2-9.4
Platelets	$10^3/\mu\text{L}$	181	904	137	638-1177
RDW	%	179	12.7	1.1	11.1-15.2
MCHC	g/dL	181	34.9	1.2	32.9-37.5
MCH	pg	181	18.7	0.8	17.1-20.4
Hematocrit	%	181	45	3.5	39.6-52.5
Hemoglobin	g/dL	181	15.7	1	13.7-17.6
Red Blood Cells	$10^6/\mu\text{L}$	181	8.39	0.67	7.27-9.65
White Blood Cells	$10^3/\mu\text{L}$	181	4.52	1.81	1.96-8.25
MCV	fL(μm^3)	181	53.5	2.4	48.9-57.9
Neutrophils	$10^3/\mu\text{L}$	179	0.68	0.33	0.22-1.57
Lymphocytes	$10^3/\mu\text{L}$	181	3.63	1.56	1.41-7.11
Monocytes	$10^3/\mu\text{L}$	179	0.08	0.04	0.03-0.18
Eosinophils	$10^3/\mu\text{L}$	180	0.06	0.04	0.01-0.16
Basophils	$10^3/\mu\text{L}$	181	0.02	0.01	0-0.05
Reticulocytes	$10^9/\text{L}$	163	238	61.7	152.3-381.5
CHCM	g/dL	181	35.3	1.2	33-37.7
CH	pg	181	18.9	0.8	17.4-20.3
HDW	g/dL	181	2.7	0.37	2.04-3.49
PDW	%	181	52.9	5.5	43.2-64.3
% Neutrophils	%	178	15.5	5.5	6.2-26.7
% Lymphocytes	%	179	80.2	6.3	66.6-90.3
% Monocytes	%	179	1.9	0.7	0.8-3.8
% Eosinophils	%	179	1.3	0.8	0.2-3.5
% Basophils	%	181	0.3	0.2	0-0.8
% Large unstained cells	%	176	0.5	0.2	0.1-1.1
Large unstained cells	$10^3/\mu\text{L}$	174	0.02	0.01	0.01-0.06
% Reticulocytes	%	163	2.9	0.8	1.7-4.9

Table 4: Hematology Data: Rats 8-16 Weeks Old - Females

TEST	UNIT	N	MEAN	S.D.	RANGE
MPV	fL(μm^3)	176	7.8	0.9	6.2-9.8
Platelets	$10^3/\mu\text{L}$	175	929	133	680-1200
RDW	%	176	12.2	1.2	10.5-14.9
MCHC	g/dL	176	35.3	1.3	33.2-37.9
MCH	pg	176	19	0.8	17.8-20.9
Hematocrit	%	176	43.3	3.1	37.9-49.9
Hemoglobin	g/dL	176	15.2	0.9	13.7-16.8
Red Blood Cells	$10^6/\mu\text{L}$	176	8.02	0.53	7.07-9.03
White Blood Cells	$10^3/\mu\text{L}$	176	3.12	1.49	1.13-7.49
MCV	fL(μm^3)	176	53.8	2.3	49.9-58.3
Neutrophils	$10^3/\mu\text{L}$	174	0.46	0.31	0.15-1.5
Lymphocytes	$10^3/\mu\text{L}$	176	2.5	1.21	0.82-5.66
Monocytes	$10^3/\mu\text{L}$	175	0.06	0.03	0.02-0.16
Eosinophils	$10^3/\mu\text{L}$	175	0.05	0.03	0.01-0.15
Basophils	$10^3/\mu\text{L}$	176	0.01	0.01	0-0.03
Reticulocytes	$10^9/\text{L}$	156	216.6	57	129.8-383.7
CHCM	g/dL	176	35.7	1.3	33.3-38.1
CH	pg	176	19.2	0.7	18.1-20.9
HDW	g/dL	176	2.31	0.25	1.88-2.81
PDW	%	176	52.7	5.5	42.2-64.4
% Neutrophils	%	175	15.4	6.4	7.1-33.2
% Lymphocytes	%	175	80	6.7	62.2-90
% Monocytes	%	176	2	0.8	0.8-3.9
% Eosinophils	%	174	1.7	1	0.5-4.5
% Basophils	%	176	0.3	0.2	0-0.8
% Large unstained cells	%	171	0.5	0.2	0.1-0.9
Large unstained cells	$10^3/\mu\text{L}$	172	0.01	0.01	0-0.04
% Reticulocytes	%	156	2.7	0.8	1.7-4.7

Table 5: Serum Chemistry Data: Rats 8-16 Weeks Old - Males

TEST	UNIT	N	MEAN	S.D.	RANGE
Phosphorus	mg/dL	164	8.04	1.22	5.58-10.41
Calcium	mg/dL	165	10.4	0.5	9.5-11.5
Total Protein	g/dL	164	6	0.5	5.2-7.1
Triglycerides	mg/dL	163	44	21	20-114
Cholesterol	mg/dL	165	58	13	37-85
Glucose	mg/dL	165	123	38	70-208
Creatinine	mg/dL	163	0.3	0.1	0.2-0.5
Indirect Bilirubin	mg/dL	139	0.06	0.03	0.01-0.12
Direct Bilirubin	mg/dL	109	0.04	0.01	0.03-0.05
Total Bilirubin	mg/dL	165	0.09	0.03	0.05-0.15
Alkaline Phosphatase	U/L	163	113	44	62-230
Aspartate Aminotransferase	U/L	164	105	20	74-143
Alanine Aminotransferase	U/L	164	28	7	18-45
Creatine Kinase	U/L	45	658	343	162-1184
Albumin	g/dL	164	4	0.4	3.4-4.8
Globulin	g/dL	144	2	0.2	1.5-2.5
A/G Ratio	ratio	144	1.99	0.29	1.58-2.67
Urea	mg/dL	164	17.1	2.9	12.3-24.6
Sodium	mmol/L	165	146	2	142-151
Potassium	mmol/L	165	4.48	0.44	3.82-5.55
Chloride	mmol/L	165	103	1	100-106

Table 6: Serum Chemistry Data: Rats 8-16 Weeks Old - Females

TEST	UNIT	N	MEAN	S.D.	RANGE
Phosphorus	mg/dL	158	7.92	1.51	5.02-10.7
Calcium	mg/dL	159	10.5	0.4	9.7-11.2
Total Protein	g/dL	159	6.3	0.5	5.5-7.7
Triglycerides	mg/dL	159	28	8	14-46
Cholesterol	mg/dL	159	48	13	24-73
Glucose	mg/dL	159	117	25	76-175
Creatinine	mg/dL	159	0.4	0.1	0.2-0.6
Indirect Bilirubin	mg/dL	133	0.08	0.03	0.03-0.15
Direct Bilirubin	mg/dL	95	0.04	0.01	0.03-0.06
Total Bilirubin	mg/dL	157	0.11	0.03	0.05-0.18
Alkaline Phosphatase	U/L	159	59	28	26-147
Aspartate Aminotransferase	U/L	158	102	31	65-203
Alanine Aminotransferase	U/L	157	25	9	16-48
Creatine Kinase	U/L	46	575	260	163-1085
Albumin	g/dL	159	4.4	0.5	3.6-5.5
Globulin	g/dL	139	2	0.2	1.5-2.4
A/G Ratio	ratio	139	2.2	0.34	1.71-3
Urea	mg/dL	158	19.3	3.7	13.2-27.1
Sodium	mmol/L	159	144	2	140-150
Potassium	mmol/L	158	4.07	0.37	3.31-4.9
Chloride	mmol/L	159	103	2	100-107

Table 7: Coagulation Data: Rats 17 Weeks of Age or Greater - Males

TEST	UNIT	N	MEAN	S.D.	RANGE
Fibrinogen	mg/dL	141	148.1	14.5	115.7-173
Prothrombin Time	sec	153	13.94	1.02	11.55-16.1
Activated Partial Prothrombin Time	sec	152	24.59	4.81	17.4-34.4

Table 8: Coagulation Data: Rats 17 Weeks of Age or Greater - Females

TEST	UNIT	N	MEAN	S.D.	RANGE
Fibrinogen	mg/dL	135	122.9	12.4	100.6-145.9
Prothrombin Time	sec	148	13.34	0.94	11.3-15.2
Activated Partial Prothrombin Time	sec	148	21.8	4.43	16.3-36.2

Table 9: Hematology Data: Rats 17 Weeks of Age or Greater - Males

TEST	UNIT	N	MEAN	S.D.	RANGE
MPV	fL(μm^3)	166	7.6	0.9	6.1-9.5
Platelets	$10^3/\mu\text{L}$	167	846	160	574-1253
RDW	%	164	13	1.1	11.6-16.2
MCHC	g/dL	167	35.1	1.5	31.9-38.5
MCH	pg	167	17.8	0.8	16.3-19.5
Hematocrit	%	167	44.2	3.4	38.5-52
Hemoglobin	g/dL	167	15.5	1	13.6-17.4
Red Blood Cells	$10^6/\mu\text{L}$	167	8.69	0.66	7.62-9.99
White Blood Cells	$10^3/\mu\text{L}$	165	4.28	2.14	1.98-11.06
MCV	fL(μm^3)	167	50.7	2.3	46.3-56.2
Neutrophils	$10^3/\mu\text{L}$	165	0.87	0.42	0.33-1.89
Lymphocytes	$10^3/\mu\text{L}$	165	3.19	1.89	1.19-9.45
Monocytes	$10^3/\mu\text{L}$	167	0.09	0.06	0.03-0.27
Eosinophils	$10^3/\mu\text{L}$	166	0.07	0.04	0.01-0.19
Basophils	$10^3/\mu\text{L}$	166	0.01	0.01	0-0.04
Reticulocytes	$10^9/\text{L}$	156	166.5	28.8	120.8-237.1
CHCM	g/dL	167	35.3	1.4	32.4-37.8
CH	pg	167	17.9	0.8	16.5-19.4
HDW	g/dL	167	2.75	0.29	2.22-3.29
PDW	%	167	55.9	6.6	45.6-71.4
% Neutrophils	%	167	22.2	10	9-49.3
% Lymphocytes	%	167	73.3	10.6	44.7-87.1
% Monocytes	%	166	2	0.7	1-3.6
% Eosinophils	%	166	1.7	0.9	0.4-4
% Basophils	%	167	0.3	0.2	0-0.6
% Large unstained cells	%	165	0.5	0.3	0.1-1.2
Large unstained cells	$10^3/\mu\text{L}$	162	0.02	0.02	0-0.07
% Reticulocytes	%	156	1.9	0.3	1.4-2.8

Table 10: Hematology Data: Rats 17 Weeks of Age or Greater - Females

TEST	UNIT	N	MEAN	S.D.	RANGE
MPV	fL(μm^3)	165	7.9	0.9	6.4-9.5
Platelets	$10^3/\mu\text{L}$	165	836	132	599-1144
RDW	%	165	12	1	10.6-14.6
MCHC	g/dL	166	35.1	1.1	33.2-37.8
MCH	pg	166	18.8	0.7	17.6-20.3
Hematocrit	%	166	43.9	2.9	38.5-49.2
Hemoglobin	g/dL	166	15.4	0.9	13.7-17.2
Red Blood Cells	$10^6/\mu\text{L}$	166	8.2	0.55	7.16-9.24
White Blood Cells	$10^3/\mu\text{L}$	165	2.67	1.62	0.96-7.88
MCV	fL(μm^3)	166	53.6	1.7	50.3-57
Neutrophils	$10^3/\mu\text{L}$	164	0.47	0.25	0.15-1.11
Lymphocytes	$10^3/\mu\text{L}$	165	2.06	1.41	0.68-6.8
Monocytes	$10^3/\mu\text{L}$	163	0.05	0.03	0.01-0.13
Eosinophils	$10^3/\mu\text{L}$	165	0.05	0.03	0.01-0.14
Basophils	$10^3/\mu\text{L}$	163	0.01	0.01	0-0.02
Reticulocytes	$10^9/\text{L}$	154	186.4	47.8	108.3-312.6
CHCM	g/dL	166	35.5	1.2	33.3-38.1
CH	pg	166	19	0.6	17.9-20.2
HDW	g/dL	166	2.27	0.18	1.95-2.59
PDW	%	166	55.9	5.8	46.8-68.5
% Neutrophils	%	165	19.3	8.3	8.8-43.8
% Lymphocytes	%	165	75.8	9.3	48.9-88.1
% Monocytes	%	165	2	0.7	1-3.6
% Eosinophils	%	165	1.9	1.2	0.3-4.7
% Basophils	%	166	0.2	0.2	0-0.7
% Large unstained cells	%	164	0.4	0.3	0-1
Large unstained cells	$10^3/\mu\text{L}$	162	0.01	0.01	0-0.05
% Reticulocytes	%	154	2.3	0.6	1.4-3.9

Table 11: Serum Chemistry Data: Rats 17 Weeks of Age or Greater - Males

TEST	UNIT	N	MEAN	S.D.	RANGE
Phosphorus	mg/dL	78	6.23	1.24	3.64-8.4
Calcium	mg/dL	78	10.3	0.7	9.1-11.9
Total Protein	g/dL	77	6.3	0.5	5.6-7.6
Triglycerides	mg/dL	77	62	32	27-160
Cholesterol	mg/dL	68	59	15	37-95
Glucose	mg/dL	78	141	19	106-184
Creatinine	mg/dL	88	0.4	0.1	0.3-0.5
Indirect Bilirubin	mg/dL	66	0.06	0.03	0-0.1
Direct Bilirubin	mg/dL	47	0.04	0.01	0.03-0.06
Total Bilirubin	mg/dL	78	0.1	0.04	0.04-0.2
Alkaline Phosphatase	U/L	88	66	21	36-131
Aspartate Aminotransferase	U/L	88	96	24	63-175
Alanine Aminotransferase	U/L	87	30	8	19-48
Lactate Dehydrogenase	U/L	10	1305	510	272-1965
Creatine Kinase	U/L	46	846	246	460-1230
MG	mg/dL	15	2.1	0.1	1.9-2.2
Lipase	U/L	10	9	2	7-14
Amylase	U/L	10	1557	316	1223-2109
Albumin	g/dL	78	4.1	0.3	3.6-4.7
Globulin	g/dL	66	2.1	0.2	1.8-2.5
A/G Ratio	ratio	66	1.91	0.24	1.5-2.33
Urea	mg/dL	87	15.7	2.3	10.7-20
Sodium	mmol/L	78	143	2	137-147
Potassium	mmol/L	78	4.55	0.53	3.88-6.11
Chloride	mmol/L	78	103	2	98-106

Table 12: Serum Chemistry Data: Rats 17 Weeks of Age or Greater - Females

TEST	UNIT	N	MEAN	S.D.	RANGE
Phosphorus	mg/dL	77	6.66	1.15	4.53-9.51
Calcium	mg/dL	77	10.6	0.7	9.5-12.1
Total Protein	g/dL	77	6.6	0.7	5.7-8.3
Triglycerides	mg/dL	76	42	35	16-175
Cholesterol	mg/dL	67	50	19	23-97
Glucose	mg/dL	77	119	16	89-163
Creatinine	mg/dL	88	0.4	0.1	0.3-0.6
Indirect Bilirubin	mg/dL	65	0.08	0.03	0.02-0.13
Direct Bilirubin	mg/dL	50	0.04	0.01	0.03-0.07
Total Bilirubin	mg/dL	77	0.13	0.04	0.07-0.21
Alkaline Phosphatase	U/L	87	30	11	18-62
Aspartate Aminotransferase	U/L	87	101	36	64-222
Alanine Aminotransferase	U/L	87	30	15	14-64
Lactate Dehydrogenase	U/L	10	971	438	256-1552
Creatine Kinase	U/L	45	702	261	218-1320
MG	mg/dL	15	2.2	0.1	1.9-2.4
Lipase	U/L	11	7	0	7-8
Amylase	U/L	11	1211	215	866-1642
Albumin	g/dL	77	4.6	0.5	3.7-5.8
Globulin	g/dL	65	1.9	0.2	1.6-2.3
A/G Ratio	ratio	65	2.31	0.34	1.64-3.07
Urea	mg/dL	88	17.5	3.9	11.7-25
Sodium	mmol/L	77	141	3	135-146
Potassium	mmol/L	77	4.07	0.42	3.37-5.11
Chloride	mmol/L	77	102	3	97-106

