



Stability in rodent breeding programs is paramount in today's research environment. Genetic drift, opportunistic infection and phenotypic characteristics are critical variables that can impact a protocol. To meet this challenge, the Global Alliance for Laboratory Animal Standardization (GALAS<sup>™</sup>) was formed to standardize the outbred Wistar Hannover rat for use in the two-year rodent bioassay. This international partnership includes Taconic US, Taconic Europe and CLEA Japan. This same partnership has already been successful in the sharing and distribution of another important toxicology model, the rasH2 (CB6F1/Jic-TgrasH2@Tac) mouse. What does this partnership result in? Toxicological data gathered from GALAS models around the world are comparable. More reliable data assures confidence in the scientific end results.

Through this collaborative effort of GALAS' experienced breeding partners, there is global awareness of the consistency of the Wistar Hannover rat in several major categories:

- **Genetic Quality Control**- The Central Institute for Experimental Animals (CIEA), Tokyo, Japan, developed a comprehensive program for genetic monitoring of the GALAS Wistar Hannover stock. An extensive genetic profile was initially determined by CIEA. After a derivation, the colony is tested to assure that it matches the determined population genetic profile. Annually after that, colonies are tested for a critical subset of loci to verify their presence in the population.
- **Husbandry** - The colonies are bred using the Poiley system which prevents mating of closely related animals. The breeding population is divided into 12 groups with a minimum of 12 monogamous breeding pairs per group. To prevent genetic drift between colonies, each colony is regularly restarted with new breeders from cryopreserved embryos or the original source colony.
- **Health Status** – Every GALAS Wistar Hannover rat colony is extensively monitored for the presence of numerous opportunistic microorganisms that are known to be pathogenic under a variety of study conditions. A complete list of tolerated/not tolerated agents for Wistar Hannover colonies in the United States is included in this package.
- **Phenotypic monitoring** – Periodically, every Wistar Hannover colony has basic physiologic parameters measured to further ensure stability. Pages (#-#) of this document reports historical control data from several of these colonies. Included in this data is longevity, body weights, histology, organ weights, clinical chemistry, neoplastic tumor data and reproductive data.

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# Taconic

Quality Laboratory Animals and Services for Research

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<b>Taconic Health Standards™</b>	<b>Germfree GF</b>	<b>Defined Flora DF</b>	<b>Restricted Flora™ RF™</b>	<b>Murine Pathogen Free™ MPF™</b>	<b>Virus-Free VF</b>
<b>Microorganisms</b>	<b>Accepted?</b>	<b>Accepted?</b>	<b>Accepted?</b>	<b>Accepted?</b>	<b>Accepted?</b>
<b>Commensal Microflora</b>					
Altered Schaedler Flora	No	Yes	Yes	Yes	Yes
Dimorphic Yeast	No	Yes	Yes	Yes	Yes
Mold	No	Yes	Yes	Yes	Yes
Aerobic spore forming bacteria	No	Yes	Yes	Yes	Yes
Anaerobic spore forming bacteria	No	Yes	Yes	Yes	Yes
Non-spore forming rod bacteria	No	No	Yes	Yes	Yes
Cocci bacteria	No	No	Yes	Yes	Yes
<b>Viruses</b>					
Mouse Hepatitis Virus (MHV)	No	No	No	No	No
Mouse Minute [parvo] Virus (MMV)	No	No	No	No	No
Mouse Parvovirus (MPV)	No	No	No	No	No
Mouse Rotavirus (EDIM)	No	No	No	No	No
Kilham's Rat Virus (KRV)	No	No	No	No	No
Rat Coronavirus (RCV)	No	No	No	No	No
Rat Parvovirus (RPV)	No	No	No	No	No
Sialodacryoadenitis Virus (SDAV)	No	No	No	No	No
Toolan's H-1 Parvovirus (TH1)	No	No	No	No	No
Encephalomyelitis Virus (GD7)	No	No	No	No	No
Pneumonia Virus of Mice (PVM)	No	No	No	No	No
Sendai Virus (SEN)	No	No	No	No	No
Lymphocytic Choriomeningitis Virus (LCM)	No	No	No	No	No
Ectromelia Virus (ECTR)	No	No	No	No	No
Hantaan Virus (HAN)	No	No	No	No	No
Mouse Adenovirus (FL) (MAV1)	No	No	No	No	No
Mouse Adenovirus (K87) (MAV2)	No	No	No	No	No
Mouse Cytomegalovirus (MCMV)	No	No	No	No	No
Respiratory Enteric Virus III (REO3)	No	No	No	No	No
K Virus (KV)	No	No	No	No	No
Lactic Dehydrogenase Elevating Virus (LDHV)	No	No	No	No	No
Polyoma Virus (POLY)	No	No	No	No	No
Thymic Virus (THY)	No	No	No	No	No
<b>Bacteria, mycoplasma, fungi</b>					
β hemolytic Streptococcus	No	No	No <sup>3</sup>	Yes	Yes
<i>Bordetella bronchiseptica</i>	No	No	No	No	Yes
<i>Citrobacter rodentium</i>	No	No	No	No	Yes
<i>Clostridium piliforme</i>	No	No	No	No	No
<i>Corynebacterium kutscheri</i>	No	No	No	No	Yes
<i>Klebsiella oxytoca</i>	No	No	No <sup>3</sup>	Yes	Yes
<i>Klebsiella pneumoniae</i>	No	No	No <sup>3</sup>	Yes	Yes
<i>Mycoplasma sp.</i>	No	No	No	No	No
<i>Pseudomonas aeruginosa</i>	No	No	No <sup>3</sup>	Yes	Yes
<i>Salmonella sp.</i>	No	No	No	No	No
<i>Staphylococcus aureus</i>	No	No	No <sup>3</sup>	Yes <sup>2</sup>	Yes
<i>Streptobacillus moniliformis</i>	No	No	No	No	No
<i>Streptococcus pneumoniae</i>	No	No	No	No	Yes
<i>Cilia Associated Respiratory Bacillus (CARB)</i>	No	No	No	No	Yes
<i>Corynebacterium bovis</i>	No	No	No <sup>1</sup>	Yes <sup>2</sup>	Yes
<i>Helicobacter sp.</i>	No	No	No	No	Yes
<i>Pasteurella pneumotropica</i>	No	No	No	No	Yes
Other <i>Pasteurella sp.</i>	No	No	Yes	Yes	Yes
<i>Pneumocystis carinii</i>	No	No	No	Yes <sup>2</sup>	Yes
<b>Parasites</b>					
<i>Aspiculuris sp.</i>	No	No	No	No	No
<i>Eimeria sp.</i>	No	No	No	No	Yes
<i>Entamoeba muris</i>	No	No	No	No	Yes
<i>Giardia muris</i>	No	No	No	No	Yes
<i>Hymenolepis sp.</i>	No	No	No	No	No
<i>Klossiella muris</i>	No	No	No	No	Yes
<i>Liponyssus sp.</i>	No	No	No	No	No
<i>Myobia sp.</i>	No	No	No	No	No
<i>Myocoptes sp.</i>	No	No	No	No	No
<i>Notoedres sp.</i>	No	No	No	No	No
<i>Polyplax sp.</i>	No	No	No	No	No
<i>Psorergates sp.</i>	No	No	No	No	No
<i>Radfordia sp.</i>	No	No	No	No	No
<i>Spironucleus sp.</i>	No	No	No	No	Yes
<i>Syphacia sp.</i>	No	No	No	No	No
Trichomonads	No	No	No	No	Yes
<i>Trichosomoides crassicauda</i>	No	No	No	No	Yes
<i>Encephalitozoon cuniculi</i>	No	No	No	No	Yes
<i>Eperythrozoon coccoides</i>	No	No	No	No	Yes
<i>Hemobartonella muris</i>	No	No	No	No	Yes

<sup>1</sup> Only applies to immunodeficient mice and rats carrying the nude or scid mutation.

<sup>2</sup> Not accepted in Barrier Units housing mice and rats with the nude or scid mutation.

<sup>3</sup> When detected, this organism will be eliminated from the Barrier Unit via a Test and Cull procedure or recycling of the colony.

**Control Data of  
BrlHan:WIST@Tac(GALAS) Rat**

**Taconic Farms, Inc.  
2005**

## Environmental Conditions and Investigation Items

### Environmental Conditions (Isolated Barrier Unit® System)

Temperature:	68 – 72° F
Humidity:	30 – 70 %
Air Filtration:	HEPA, 100% fresh
Ventilation Rate:	15 – 20 air changes per hour
Light Cycle:	12 hours on: 12 hours off
Caging:	Breeding 10.5 x 19.0 x 8.0 Holding 10.5 x 19.0 x 8.0
Diet:	NIH-31 Diet, Autoclaved (121°C, 25 min.), <i>ad libitum</i>
Water:	Chlorinated to 5 to 10 ppm, <i>ad libitum</i>

### Investigation Items

Table 1a	Body weight (3 to 36 weeks of age) *Study was terminated at week 36. Study was restarted in April 2003.
Table 1b	Body weight (3 to 106 weeks of age)
Figure 1a	Body weight curve (3 to 36 weeks of age)
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**Table 1a**      **Body weight**

Weeks	Male			Female			Weeks	Male			Female		
	n	Mean	SD	n	Mean	SD		n	Mean	SD	n	Mean	SD
3	30	43.7	2.7	30	42.8	2.4	28	30	474.0	54.2	30	268.1	29.1
4	30	78.0	5.0	30	72.9	4.0	29	30	478.3	55.8	30	269.2	28.7
5	30	120.9	7.4	30	104.0	6.0	30	30	484.8	57.0	30	270.5	27.2
6	30	166.7	9.6	30	130.1	9.3	31	30	491.4	58.7	30	274.1	29.3
7	30	213.5	13.5	30	153.1	11.4	32	30	491.6	60.9	30	273.8	29.8
8	30	254.6	18.4	30	170.8	12.8	33	30	499.8	62.4	30	277.3	30.6
9	30	285.7	21.9	30	186.4	14.1	34	30	505.1	63.9	30	278.9	31.1
10	30	314.3	25.6	30	199.6	16.0	35	30	510.0	66.5	30	282.5	32.5
11	30	337.2	28.2	30	211.5	17.8	36	30	517.0	67.6	30	285.7	33.6
12	30	356.2	30.8	30	220.1	18.2							
13	30	366.5	33.4	30	224.1	19.0							
14	30	381.8	35.5	30	231.2	19.5							
15	30	384.7	41.6	30	233.8	20.2							
16	30	395.0	38.6	30	236.2	21.2							
17	30	406.7	40.2	30	241.2	20.4							
18	30	413.6	42.0	30	244.3	22.4							
19	30	419.3	43.6	30	246.5	23.1							
20	30	430.4	43.7	30	248.1	22.9							
21	30	432.5	60.2	30	254.0	23.9							
22	30	452.8	53.8	30	257.1	24.8							
23	30	453.2	49.3	30	255.8	20.5							
24	30	460.3	50.7	30	262.1	27.0							
25	30	462.8	52.0	30	262.7	26.7							
26	30	466.6	52.7	30	264.0	26.9							
27	30	461.2	68.7	30	265.8	28.8							

- Data collected June 19, 2001 through February 5, 2002
- Housing 3 to 5 weeks of age 10 per cage, 6 to 36 weeks of age, 5 per cage

**Table 1b Body weight**

Weeks	Male			Female			Weeks	Male			Female		
	n	Mean	SD	n	Mean	SD		n	Mean	SD	n	Mean	SD
3	55	52.6	4.9	50	50.1	5.4	55	34	616.1	52.5	35	334.0	40.5
4	55	86.9	8.1	50	79.8	7.5	56	34	619.3	53.2	35	331.8	43.1
5	55	129.3	11.7	50	110.9	9.6	57	34	619.9	53.7	35	330.0	40.7
6	55	168.6	15.9	50	132.4	10.4	58	34	622.0	53.8	35	329.7	39.7
7	55	212.6	19.6	50	154.6	12.0	59	34	624.6	55.0	35	330.1	40.7
8	55	254.8	23.1	50	173.9	13.7	60	34	623.9	55.6	35	329.5	40.8
9	55	282.4	25.7	50	187.9	15.1	61	34	622.0	55.8	35	329.9	39.5
10	55	314.3	27.5	50	201.6	15.2	62	34	625.7	57.3	35	330.3	40.9
11	55	334.8	29.1	50	211.4	15.5	63	34	625.9	58.2	35	332.9	39.8
12	55	355.6	31.0	50	219.7	16.5	64	34	629.2	58.2	35	333.1	41.3
13	55	372.2	32.3	50	225.5	16.6	65	34	630.3	58.8	35	335.8	41.5
14	55	390.6	34.6	50	232.5	16.9	66	34	629.0	60.1	35	336.4	41.6
15	55	401.8	36.5	50	236.7	17.0	67	34	630.1	59.9	35	336.5	40.6
16	55	412.6	37.5	50	241.1	18.2	68	34	635.5	61.1	35	339.6	41.7
17	55	421.2	37.3	50	245.4	18.1	69	34	638.3	62.0	35	340.4	41.7
18	55	433.9	39.3	50	250.8	17.4	70	34	645.1	63.0	35	342.4	43.4
19	55	439.1	39.8	50	250.9	17.5	71	34	644.4	63.5	35	342.7	43.1
20	55	444.3	40.5	50	251.5	18.0	72	34	650.6	64.0	35	343.8	44.2
21	55	453.1	41.6	50	255.5	18.2	73	34	654.0	64.5	35	343.7	41.4
22	52	461.2	43.5	50	257.3	18.3	74	34	658.1	66.2	35	347.5	45.4
23	52	467.0	44.5	50	258.4	18.9	75	34	658.3	66.5	35	349.0	44.3
24	52	476.6	44.9	50	262.6	20.2	76	34	661.2	66.9	35	349.0	46.2
25	52	479.3	45.1	50	263.8	19.9	77	34	659.2	66.5	35	347.5	50.7
26	52	486.5	46.7	50	267.0	20.5	78	34	662.3	68.3	35	348.7	45.6
27	52	492.5	47.6	50	270.3	19.9	79	34	663.4	69.0	35	352.1	46.3
28	52	497.6	48.6	50	272.6	21.1	80	34	662.8	69.1	35	350.2	46.8
29	52	501.9	48.6	50	273.4	21.3	81	34	663.5	69.1	34	361.1	46.8
30	52	507.0	48.4	50	274.8	21.8	82	34	661.8	69.1	34	364.9	47.6
31	52	509.9	48.1	50	276.5	22.3	83	34	659.7	69.3	33	370.2	48.3
32	52	516.4	50.2	50	277.9	23.1	84	34	662.7	70.6	33	368.6	55.0
33	52	523.1	51.6	50	282.2	24.5	85	34	668.5	71.0	33	374.9	49.7
34	50	526.5	52.0	50	282.5	24.3	86	34	674.9	71.8	33	384.7	52.4
35	50	529.8	52.6	50	283.7	26.7	87	34	683.5	72.2	33	388.3	51.6
36	50	535.1	53.9	50	288.1	26.0	88	34	683.5	74.7	33	383.9	50.8
37	50	542.2	54.0	50	289.9	27.8	89	34	688.9	77.1	33	382.1	51.2
38	50	544.7	54.6	50	293.0	29.8	90	33	691.2	80.2	32	388.0	55.5
39	50	550.4	55.7	50	293.3	31.3	91	33	690.6	80.9	32	389.7	53.8
40	50	555.0	55.9	50	295.1	31.4	92	33	688.1	82.9	32	391.1	52.1
41	50	559.0	56.3	50	296.6	32.1	93	33	684.3	84.9	32	386.8	51.3
42	50	561.3	57.3	50	300.6	32.2	94	33	684.3	88.0	32	385.1	51.5
43	50	562.5	61.0	50	302.1	33.9	95	33	687.1	90.9	32	397.7	68.4
44	49	573.8	59.1	50	305.2	35.5	96	33	692.0	92.6	31	390.4	54.5
45	49	574.9	60.4	50	308.3	36.4	97	33	695.0	94.7	30	396.4	53.1
46	49	580.5	61.1	50	311.9	38.1	98	33	693.0	96.3	30	393.0	57.9
47	49	583.4	61.9	50	313.1	37.4	99	33	693.0	98.1	29	401.1	56.9
48	49	587.7	62.8	50	314.6	38.5	100	32	691.3	99.6	28	404.0	58.2
49	49	591.9	62.8	50	316.8	38.9	101	32	705.1	82.8	27	408.3	57.7
50	49	597.2	64.1	50	319.0	39.6	102	32	706.6	84.1	27	409.7	56.7
51	49	600.0	64.6	50	321.3	41.0	103	32	711.9	85.6	27	410.7	54.5
52	49	604.7	65.1	50	324.7	41.3	104	32	713.3	89.4	27	415.5	55.2
53	49	606.9	65.5	50	328.3	43.1	105	32	712.1	93.1	27	416.5	56.1
54	49	613.4	66.5	50	331.1	44.9	106	32	709.9	94.9	27	414.7	55.9

- Data collected April 11, 2003 through April 6, 2005
- All animals have week of birth of March 17, 2003 and were sourced from I022.
- Housing 3 to 5 weeks of age 10 per cage, 6 to 13 weeks of age 5 per cage, 14 to 81 weeks of age 2-3 per cage

Figure 1a: Body weight curve, from data of Table 1a.

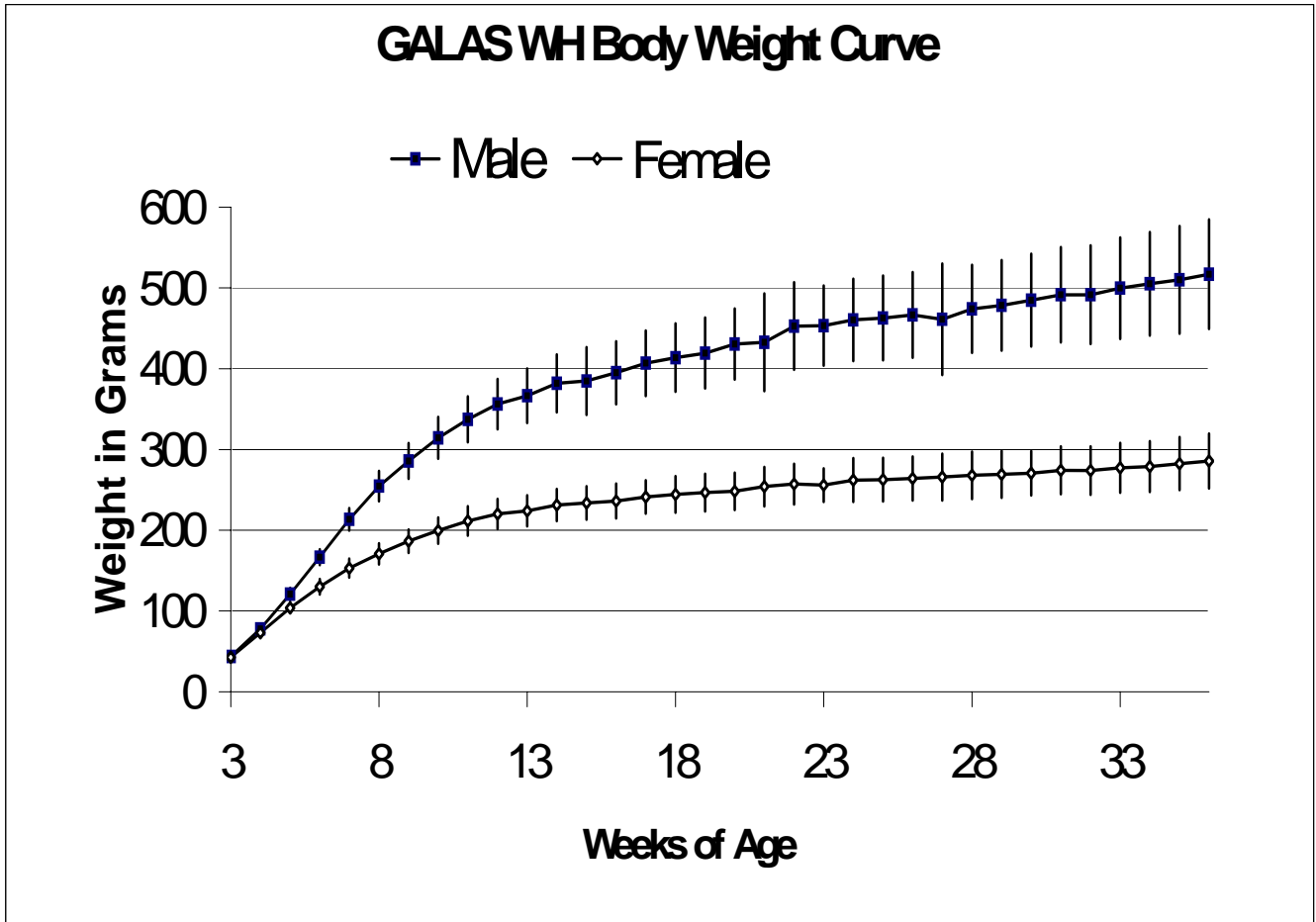
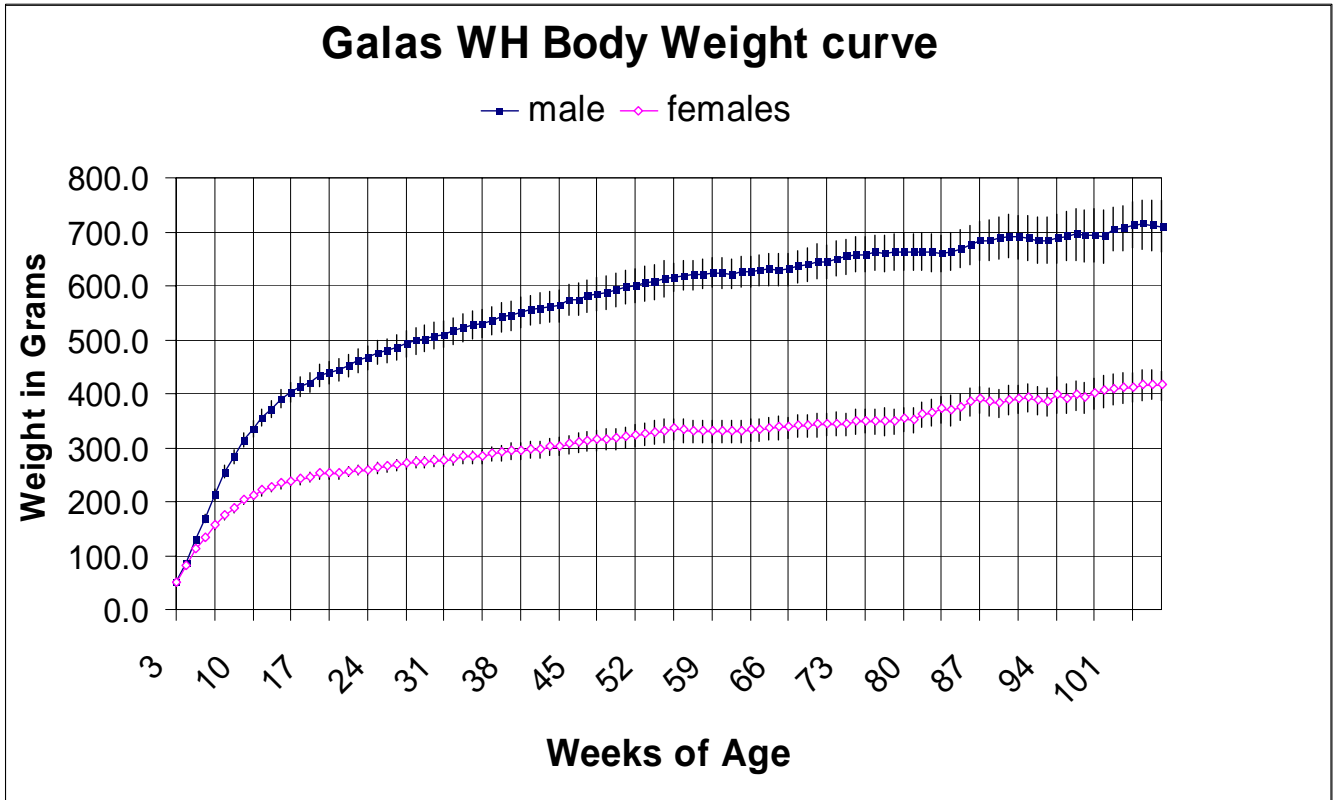
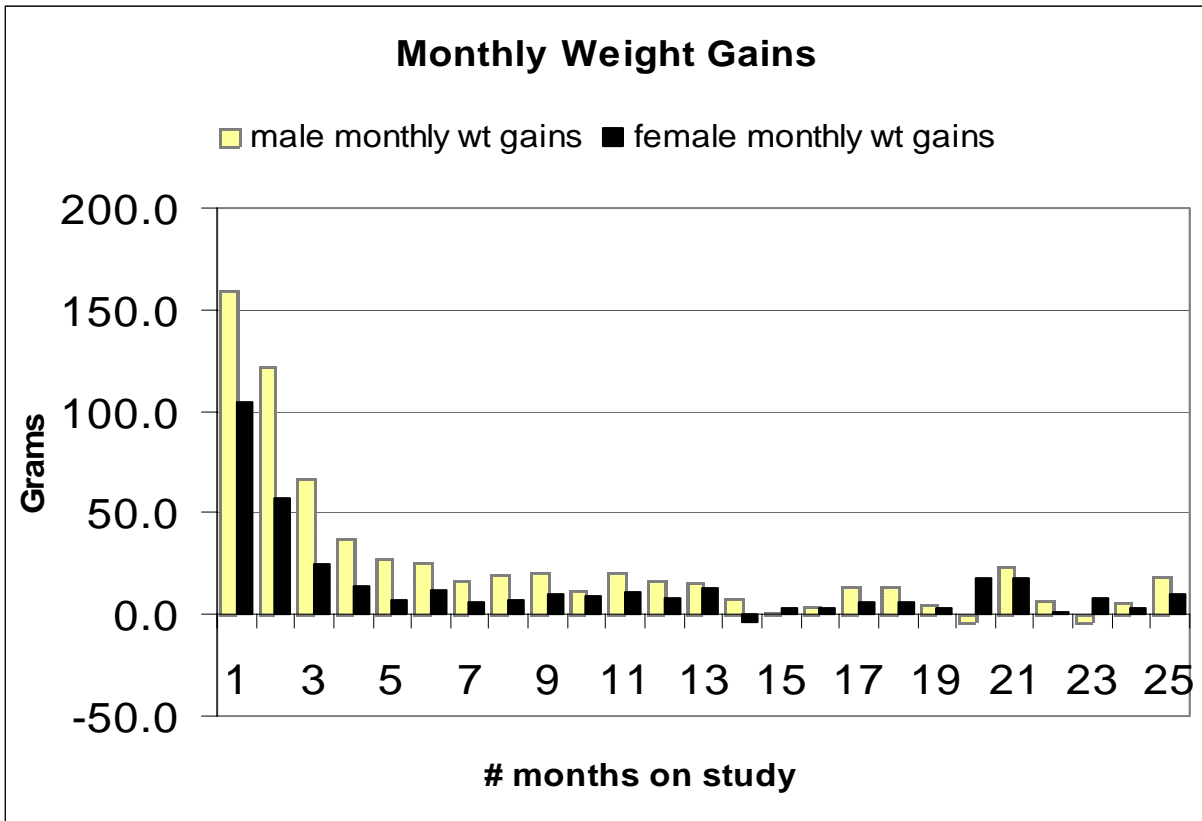




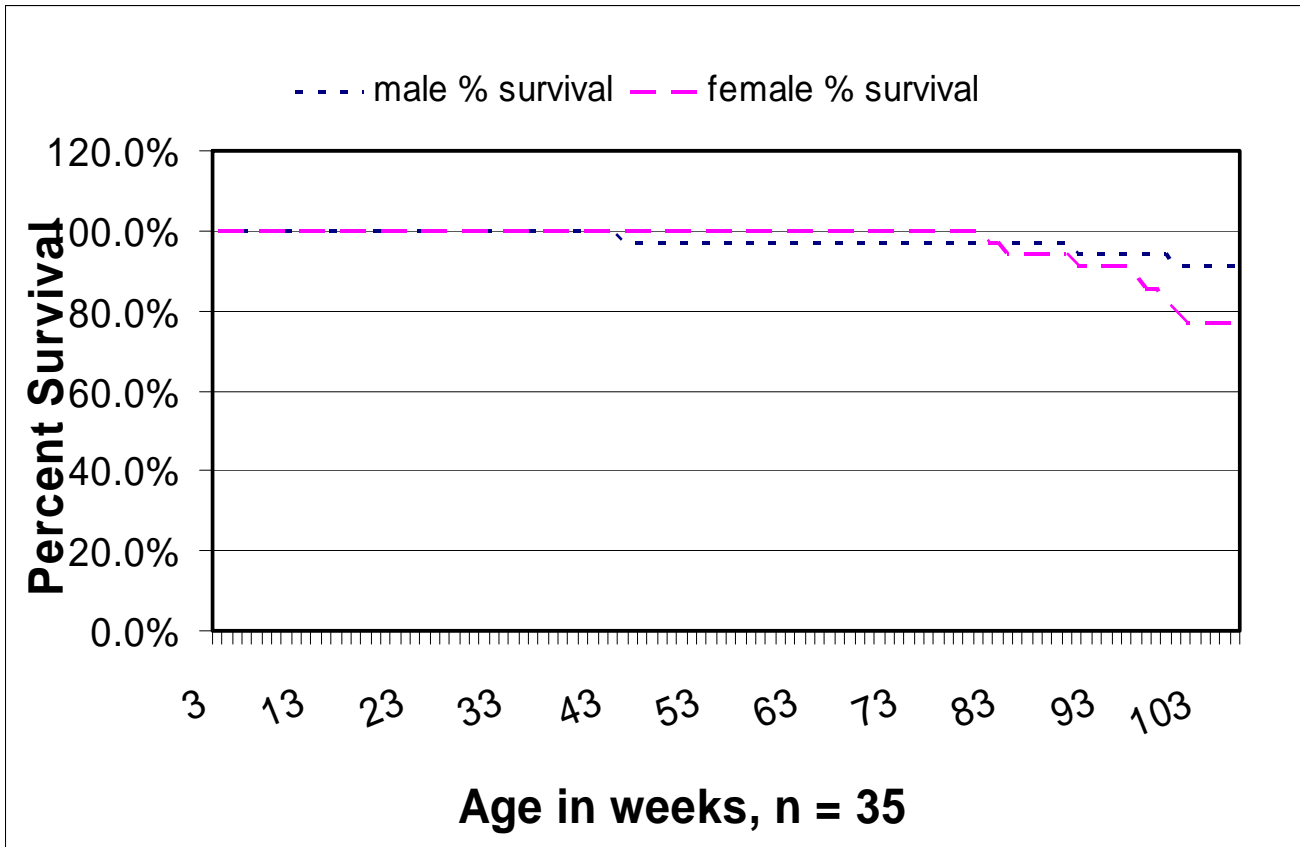
Figure 1b: Body weight curve, from Data of Table 1b.



**Figure 1c: Monthly weight gains**



**Figure 2: Survival rate**



**Table 2 Hematology**

Item	Unit	5 weeks						10 weeks					
		Male			Female			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
RBC	X10 <sup>6</sup> /μl	10	7.15	0.46	10	7.31	0.49	10	8.16	0.64	10	8.20	0.57
Hgb	g/dl	10	14.8	0.7	10	14.8	0.73	10	15.4	1.1	10	15.2	0.9
Hct	%	10	45.6	2.9	10	46.7	2.8	10	49.8	2.9	10	50.5	3.3
MCV	fl	10	64.0	2.0	10	63.8	1.2	10	61	0.8	10	61.6	1.5
MCH	pg	10	20.9	1.3	10	20.2	0.5	10	18.9	1.2	10	18.6	0.6
MCHC	%	10	32.5	1.6	10	31.7	0.4	10	30.9	1.2	10	30.2	0.8
WBC	X10 <sup>3</sup> /μl	10	6.9	1.5	10	6.8	1.6	10	10.8	2.4	10	7.1	1.5
Plat.	X10 <sup>3</sup> /μl	10	1184	183	10	1216.5	181	10	1109	83	10	1111	176

Item	Unit	19 weeks						21 weeks		
		Male			Female			Male		
		n	Mean	SD	n	Mean	SD	n	Mean	SD
RBC	X10 <sup>6</sup> /μl	8	9.42	0.33	10	8.27	0.62	3	8.54	0.28
Hgb	g/dl	8	15.9	0.9	10	14.7	0.8	3	15.0	0.2
Hct	%	8	52.5	2.9	10	48.5	3.1	3	48.7	0.8
MCV	fl	8	56.0	1.8	10	59.0	1.8	3	57	1.0
MCH	pg	8	16.8	0.7	10	17.8	0.7	3	17.6	0.6
MCHC	%	8	30.2	0.5	10	30.3	0.3	3	30.9	0.7
WBC	X10 <sup>3</sup> /μl	8	7.9	1.3	10	5.6	1.5	3	4.70	1.9
Plat.	X10 <sup>3</sup> /μl	8	919	140	10	959	165	3	809	28

Item	Unit	32 weeks					
		Male			Female		
		n	Mean	SD	n	Mean	SD
RBC	X10 <sup>6</sup> /μl	9	9.25	0.48	10	8.28	0.31
Hgb	g/dl	9	16.1	0.7	10	15.2	0.4
Hct	%	9	51.5	2.6	10	48.5	1.1
MCV	fl	9	56.0	1.4	10	59.0	1.4
MCH	pg	9	17.4	0.4	10	18.4	0.5
MCHC	%	9	31.2	0.3	10	31.4	0.4
WBC	X10 <sup>3</sup> /μl	9	7.0	0.8	10	5.2	1.1
Plat.	X10 <sup>3</sup> /μl	9	958	100	10	849	273

- Data collected August 19, 2003 to April 6, 2004.
- Blood samples collected from the abdominal aorta after carbon dioxide narcosis. Blood was placed into an EDTA coated, microtainer tube. Analyses performed by LabCorp, Research Triangle Park, NC.

**Table 2**                      **Hematology (Continued)**

Item	Unit	106 weeks					
		Male			Female		
		n	Mean	SD	n	Mean	SD
RBC	$\times 10^6/\mu\text{l}$	8	8.21	2.31	10	8.10	0.39
Hgb	g/dl	8	14.4	3.6	10	15.4	1.1
Hct	%	8	49.7	13.0	10	52.1	3.1
MCV	fl	8	61.6	5.0	10	64.3	1.8
MCH	pg	8	17.9	2.0	10	19.0	1.0
MCHC	%	8	29.1	0.9	10	29.6	1.1
WBC	$\times 10^3/\mu\text{l}$	8	12.9	19.8	10	4.7	1.5
Plat.	$\times 10^3/\mu\text{l}$	8	856	160	10	805	162

**Table 3 Serum Biochemistry**

Items	Unit	21 weeks			55 weeks					
		Male			Male			Female		
		n	Mean	SD	n	Mean	SD	N	Mean	SD
ALT	U/l	3	22	2	15	63.1	57.7	15	36.0	10.9
AST	U/l	3	65	4	15	112.0	54.5	15	109.8	49.1
ALP	U/l	3	71	6	15	70.4	12.7	15	28.6	7.6
LDH	U/l	3	77	3	15	361.2	257.3	15	289.2	126.9
ChE	IU/l	3	QNS	N/a	15	542.6	181.5	15	2413.7	892.7
CPK	U/l	3	122.0	34.9	15	322.3	200.4	15	269.1	229.7
Glucose	mg/dl	3	122.7	25.7	15	339.9	196.7	15	318.1	121.0
Tot Chol.	mg/dl	3	66.3	12.9	15	84.0	18.9	15	82.9	32.3
Phospholipid	mg/dl	3	136.7	13.6	15	141.0	31.9	15	177.7	51.3
Triglycerides	mg/dl	3	86.7	26.7	15	173.8	82.1	15	116.5	75.3
NEFA	mEq/dl	3	0.6	0.1	15	0.9	0.2	15	0.8	0.2
Ca	mg/dl	3	11.9	0.2	15	13.4	1.9	15	12.7	2.5
Na	meq/l	3	151.7	2.1	15	148.7	5.6	15	148.1	9.5
K	meq/l	3	5.7	0.3	15	7.9	0.9	15	8.9	3.0
Cl	meq/l	3	100.7	2.3	15	100.5	3.0	15	101.0	6.3
PO <sub>4</sub>	mg/dl	3	9.2	0.4	15	9.3	1.5	15	7.9	2.5
Bilirubin	mg/dl	3	0.1	0.0	15	0.1	0.0	15	0.2	0.1
BUN	mg/dl	3	15.7	1.5	15	14.9	1.5	15	19.9	3.4
Creatinine	mg/dl	3	0.3	0.1	15	0.6	0.1	15	0.5	0.1
Total Prot.	g/dl	3	7.2	0.4	15	7.1	0.6	15	7.7	0.6
Albumin	g/dl	3	4.8	0.3	15	4.6	0.3	15	5.4	0.4
Globulin	g/dl	3	2.4	0.1	15	2.5	0.3	15	2.3	0.2
A/G	ratio	3	2.0	0.1	15	1.8	0.2	15	2.3	0.1

- Data collected August 19, 2003 to April 6, 2005. Serum biochemistry was not performed on group #2.
- Blood samples collected from the abdominal aorta under carbon dioxide narcosis after an overnight fasting period. Analyses performed by LabCorp, Research Triangle Park, NC.
- Analyses performed on a Hitachi 717, Roche Diagnostics, Indianapolis, IN, Cobas Mira, Roche Diagnostics, Indianapolis, IN and Helena REP, Helena, Beaumont, TX Agarose Gel.

**Table 3 Serum Biochemistry**

Item	Unit	106 weeks					
		Male			Female		
		N	Mean	SD	n	Mean	SD
ALT	U/l	10	24.6	7.7	10	28.2	10.2
AST	U/l	10	77.7	19.3	10	88.1	42.9
ALP	U/l	10	56.3	25.2	10	29.3	11.8
LDH	U/l	10	251.0	210.	10	105.0	61.4
ChE	IU/l	10	982.3	400. 2	10	1713.2	477.5
CPK	U/l	10	338.3	370. 8	10	105.2	68.1
Glucose	mg/dl	10	132.2	30.7	10	148.6	20.4
Tot Chol.	mg/dl	10	140.4	47.3	10	75.9	14.8
Phospholipid	mg/dl	10	222.9	65.9	10	153.7	22.8
Triglycerides	mg/dl	10	209.	127. 9	10	56.1	16.8
NEFA	mEq/dl		QNS	QNS	10	QNS	QNS
Ca	mg/dl	10	11.8	0.2	10	11.7	0.2
Na	mmol/l	10	151.3	3.4	10	148.1	2.1
K	mmol/l	10	6.5	1.75	10	6.9	0.9
Cl	mmol/l	10	105.0	4.0	10	103.5	1.7
PO <sub>4</sub>	mg/dl	10	10.0	5.5	10	7.4	0.9
Bilirubin	mg/dl	10	0.2	0.0	10	0.1	0.05
BUN	mg/dl	10	41.8	82.2	10	15.0	2.0
Creatinine	mg/dl	10	1.4	3.0	10	0.4	0.1
Total Prot.	g/dl	10	6.7	0.4	10	7.1	0.4
Albumin	g/dl	10	4.1	0.4	10	4.7	0.3
Globulin	g/dl	10	2.6	0.2	10	2.4	0.3
A/G	ratio	10	1.6	0.2	10	1.9	0.2

- Data collected August 19, 2003 to April 6, 2005
- Blood samples collected from the abdominal aorta under carbon dioxide narcosis after an overnight fasting period. Analyses performed by LabCorp, Research Triangle Park, NC.
- Analyses performed on a Hitachi 717, Roche Diagnostics, Indianapolis, IN, Cobas Mira, Roche Diagnostics, Indianapolis, IN and Helena REP, Helena, Beaumont, TX Agarose Gel.

**Table 4 Urinalysis**

	21 weeks			31 weeks			55 weeks	
		Male n = 3 %		Male n = 2 %		Male n = 15 %	Female n = 15 %	
pH	5	0		0		0	0	
	6	0		0		13	60	
	6.5	67		50		67	40	
	7	33		0		20	0	
	7.5	0		50		0	0	
	8	0		0		0	0	
	8.5	0		0		0	0	
Glucose (mg/dl)	-	100		100		100	100	
	100 - 249	0		0		0	0	
	250 - 499	0		0		0	0	
	500 - 999	0		0		0	0	
	1000 - 1999	0		0		0	0	
	≥2000	0		0		0	0	
Protein (mg/dl)	-	0		0		7	53	
	Trace	33		100		47	40	
	< 30	67		0		0	0	
	30 - 99	0		0		47	7	
	100 - 299	0		0		0	0	
	300 - 1999	0		0		0	0	
	≥2000	0		0		0	0	
Urobilinogen (mg/dl)	≤ 0.2	100		50		100	100	
	1	0		50		0	0	
	2	0		0		0	0	
	4	0		0		0	0	
	≥8	0		0		0	0	
Bilirubin	-	100		50		100	93	
	+	0		50		0	7	
	++	0		0		0	0	
	+++	0		0		0	0	
Ketone (mg/dl)	-	0		0		87	100	
	5	0		50		13	0	
	15	67		50		0	0	
	40	33		0		0	0	
	80	0		0		0	0	
	≥160	0		0		0	0	
Occult blood	-	100		100		53*	93	
	Trace	0		0		7	0	
	+	0		0		13	7	
	++	0		0		0	0	
	+++	0		0		20	0	

\*animal #24 had no result noted.

- Data collected August 19, 2003 to April 6, 2004
- Urine collected using metabolic cages.
- Analyses performed on Multistix®, Bayer Corp.



**Table 4      Urinalysis**

106 weeks				
		Male n = 10 %	Female n = 10 %	
PH	5	0	0	
	6	20	40	
	6.5	70	60	
	7	10	0	
	7.5	0	0	
	8	0	0	
	8.5	0	0	
Glucose (mg/dl)	-	100	100	
	100 - 249	0	0	
	250 - 499	0	0	
	500 - 999	0	0	
	1000 - 1999	0	0	
	≥2000	0	0	
Protein (mg/dl)	-	0	0	
	< 30	20	50	
	30 - 99	30	40	
	100 - 299	20	10	
	300 - 1999	30	0	
	≥2000	0	0	
Urobilinogen (mg/dl)	≤ 0.2	100	100	
	1	0	0	
	2	0	0	
	4	0	0	
	≥8	0	0	
Bilirubin	-	100	100	
	+	0	0	
	++	0	0	
	+++	0	0	
Ketone (mg/dl)	-	100	100	
	5	0	0	
	15	0	0	
	40	0	0	
	80	0	0	
	≥160	0	0	
Occult blood	-	70	80	
	+	0	10	
	++	20	10	
	+++	10	0	

- Data collected August 19, 2003 to April 6, 2005
- Spontaneously voided urine collected using metabolic cages.
- Analyses performed on Multistix®, Bayer Corp.

**Table 5 Absolute and Relative Organ Weight**

	Unit	21 weeks			34 weeks			55 weeks					
		Male			Male			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Body weight	g	3	424.2	28.9	2	546.1	32.5	15	595.2	101.2	15	325.4	58.1
Absolute organ weight:													
Brain	g	3	2.08	0.08	2	2.19	0.06	15	2.40	0.10	15	2.23	0.23
Pituitary gland	g	3	0.01	0.00	2	0.01	0.00	15	0.02	0.01	15	0.03	0.01
Heart	g	3	1.26	0.14	2	1.57	0.03	15	1.65	0.20	15	1.01	0.09
Lungs	g	3	1.85	0.22	2	1.86	0.21	15	2.05	0.25	15	1.67	0.28
Stomach	g	3	2.04	0.16	2	3.01	0.55	15	3.08	0.45	15	2.22	0.23
Liver	g	3	11.66	1.03	2	14.90	1.78	15	16.15	3.41	15	9.43	1.37
Spleen	g	3	0.73	0.09	2	0.78	0.03	15	0.98	0.13	15	0.70	0.08
Kidney R	g	3	1.36	0.10	2	1.49	0.09	15	1.77	0.17	15	1.24	0.14
Kidney L	g	3	1.40	0.02	2	1.40	0.08	15	1.76	0.17	15	1.21	0.13
Kidneys	g	3	2.76	0.12	2	2.89	0.08	15	3.53	0.34	15	2.45	0.27
Adrenal R	g	3	0.05	0.01	2	0.04	0.01	15	0.04	0.01	15	0.05	0.01
Adrenal L	g	3	0.04	0.02	2	0.04	0.00	15	0.13	0.31	15	0.05	0.01
Adrenals	g	3	0.09	0.02	2	0.08	0.00	15	0.17	0.32	15	0.10	0.01
Seminal vesicle	g	3	0.73	0.11	2	0.89	0.01	15	1.15	0.23		N/a	N/a
Uterus	g		N/a	N/a		N/a	N/a		N/a	N/a	15	0.95	0.19
Testis R	g	3	1.95	0.14	2	1.93	0.06	15	1.87	0.30		N/a	N/a
Testis L	g	3	1.97	0.21	2	1.95	0.15	15	1.94	0.28		N/a	N/a
Ovary R	g		N/a	N/a		N/a	N/a		N/a	N/a	15	0.08	0.02
Ovary L	g		N/a	N/a		N/a	N/a		N/a	N/a	15	0.08	0.02
Urinary bladder	g	3	0.16	0.09	2	0.16	0.05	15	0.24	0.10	15	0.11	0.02
Relative organ weight to body weight													
Brain	%	3	0.49		2	0.40		15	0.40		15	0.68	
Pituitary gland	%	3	0.00		2	0.00		15	0.00		15	0.01	
Heart	%	3	0.30		2	0.29		15	0.28		15	0.31	
Lung	%	3	0.44		2	0.34		15	0.34		15	0.51	
Stomach	%	3	0.48		2	0.55		15	0.52		15	0.68	
Liver	%	3	2.75		2	2.73		15	2.71		15	2.90	
Spleen	%	3	0.17		2	0.14		15	0.17		15	0.22	
Kidney R	%	3	0.46		2	0.27		15	0.30		15	0.38	
Kidney L	%	3	0.33		2	0.26		15	0.30		15	0.37	
Kidneys	%	3	0.65		2	0.53		15	0.60		15	0.74	
Adrenal R	%	3	0.01		2	0.01		15	0.01		15	0.01	
Adrenal L	%	3	0.01		2	0.01		15	0.02		15	0.01	
Adrenals	%	3	0.02		2	0.02		15	0.03		15	0.02	
Seminal vesicle	%	3	0.17		2	0.16		15	0.19			N/a	
Uterus	%		N/a			N/a			N/a		15	0.29	
Testis R	%	3	0.46		2	0.35		15	0.31			N/a	
Testis L	%	3	0.47		2	0.36		15	0.33			N/a	
Ovary R	%		N/a			N/a			N/a		15	0.02	
Ovary L	%		N/a			N/a			N/a		15	0.02	
Urinary bladder	%	3	0.04		2	0.03		15	0.04		15	0.04	

- Data collected August 19, 2003 to April 6, 2005
- Weights collected after overnight fasting period and exsanguination

**Table 5 Absolute and Relative Organ Weight**

	Unit	106 weeks					
		Male			Female		
		n	Mean	SD	n	Mean	SD
Body weight	g	10	637.8	96.7	10	372.3	38.5
Absolute organ weight							
Brain	g		2.298	0.287		2.075	0.219
Pituitary gland	g		0.027	0.024		0.068	0.152
Heart	g		1.735	0.422		1.113	0.134
Lung	g		2.507	0.870		1.732	0.260
Stomach	g		3.548	0.518		2.549	0.317
Liver	g		17.558	2.240		9.885	1.067
Spleen	g		1.467	0.308		0.869	0.113
Kidney R	g		2.312	0.847		1.213	0.114
Kidney L	g		2.232	0.754		1.198	0.115
Kidneys	g		4.544	1.601		2.411	0.229
Adrenal R	g		0.045	0.021		0.093	0.186
Adrenal L	g		0.052	0.023		0.093	0.171
Adrenals	g		0.097	0.044		0.186	0.357
Seminal vesicle	g		0.922	9.422		N/a	N/a
Uterus	g		Na	Na		0.772	0.279
Testis R	g		1.895	0.342		N/a	N/a
Testis L	g		1.858	0.373		N/a	N/a
Ovary R	g		Na	Na		0.125	0.048
Ovary L	g		Na	Na		0.143	0.083
Urinary bladder	g		0.278	0.078		0.202	0.060
Relative organ weight to body weight							
Brain	%		0.360			0.557	
Pituitary gland	%		0.004			0.018	
Heart	%		0.272			0.299	
Lung	%		0.393			0.465	
Stomach	%		0.556			0.685	
Liver	%		2.753			2.655	
Spleen	%		0.230			0.233	
Kidney R	%		0.362			0.326	
Kidney L	%		0.350			0.322	
Kidneys	%		0.712			0.648	
Adrenal R	%		0.007			0.025	
Adrenal L	%		0.008			0.025	
Adrenals	%		0.015			0.050	
Seminal vesicle	%		0.145			Na	
Uterus	%		Na			0.207	
Testis R	%		0.297			Na	
Testis L	%		0.291			Na	
Ovary R	%		Na			0.034	
Ovary L	%		Na			0.038	
Urinary bladder	%		0.044			0.054	

- Data collected August 19, 2003 to April 6, 2005
- Weights collected after overnight fasting period and exsanguination.

**Table 6 Histopathological findings**

Organ	Findings	21 week (n-3)	55 weeks (n-15)		106 weeks (n-10)	
		Male	Male	Female	Male	Female
Heart	• Degeneration, minimal to mild, myocardium and epicardium				3	
	• Mineralization, minimal to mild, atrium, ventricle, aorta		8		1	
	• No abnormal changes	3	7	15	7	10
Liver	• Hyperplasia, bile duct, multifocal, minimal to mild		3	4	4	4
	• Microgranulomas, multifocal, minimal	1				
	• No abnormal changes	2	11	11	6	6
Kidney	• Mineralization, multifocal, minimal to mild, tubular epithelium, cortico-medullary junction			7- both kidneys 2- only on right kidney	4-both	7-both
	• Nephrosis, chronic, interstitial, minimal to mild, cortex				4-both	
	• No abnormal changes	3	15	6	2	3
Spleen	• Hematopoiesis, multifocal, mild, red pulp		15	15	2	8
	• Hyperplasia, lymphocytic, mild, periarteriolar sheaths, white pulp with hematopoiesis, mild to moderate, red pulp				8	2
	• Hemosiderosis, mild, red pulp				8	9
	• No abnormal changes	3				
Testes	• Concretions, intratubular , multifocal, minimal, seminiferous tubules		1- right side only	-		-
	• No abnormal changes	3	14		10	
Prostate Seminal Vesicles	• No abnormal changes	3	15	-	10	-
Ovary	• No abnormal changes	-	-	15	-	10
Uterus	• No abnormal changes	-	-	15	-	10

Vagina	<ul style="list-style-type: none"> <li>No abnormal changes</li> </ul>	-	-	15	-	10
Urinary Bladder	<ul style="list-style-type: none"> <li>No abnormal changes</li> </ul>	3	15	15	10	10
Tumor Masses	<ul style="list-style-type: none"> <li>No abnormal changes</li> <li>Tumor Masses</li> </ul>	-	-	-	3 *	2 **

\* Tumor Masses – Male – Epidermal Inclusion Cyst; Fibroma; Hemangioma/Sarcoma

\*\* Tumor Masses – Female – Fibroadenoma of Mammary Gland; Epidermal Inclusion Cyst

- Data collected August 19, 2003 to April 6, 2005.
- Hematoxylin and eosin staining of tissues fixed in 10 % neutral buffered formalin
- Analysis performed at Taconic Anmed, Steven Stiefel, DVM.

# **Biological Background Data of BrlHan:WIST@Jcl(GALAS) Rats**

**Examined by CLEA Japan, Inc.**

**GALAS Study Group**

**2002**

# Environmental Conditions and Items for Biological Examinations

## Environmental conditions (Barrier system)

Temperature	: 20 to 26
Humidity	: 50 to 70%
Air filter	: HEPA
Ventilation rate	: 10 to 15 times/hour
Illumination	: 200 lux/F1+800mm
Light cycle	: Light 12 hours /Dark 12 hours
Casing	: Reproduction = Econ cage (W345×D403×H177), pair mating : Rearing = Bracket cage (W260×D380×H200), group housing *3 to 5 weeks of age ;10 heads/cage *6 weeks of age and over 5 heads/cage
Diet	: CE-2 (Autoclaved 121 , 30 min), ad libitum
Water	: Chloride additional water (4 to 6ppm), ad libitum

## Items for biological examinations

Figure 1.	Body weight curve (4 to 104 weeks of age)
Figure 2.	Survival rate curve (4 to 104 weeks of age)
Table 1.	Body weight (4 to 104 weeks of age)
Table 2.	Survival rate (4 to 104 weeks of age)
Table 3.	Hematology (5, 10, 18, 31, 52 and 104 weeks of age)
Table 4.	Clinical biochemistry (5, 10, 18, 31, 52 and 104 weeks of age)
Table 5.	Urinalysis (5, 10, 18, 31, 52 and 104 weeks of age)
Table 6.	Absolute and relative organ weight (5, 10, 18, 31, 52 and 104 weeks of age)
Table 7.	Histopathological findings (5, 10, 18 and 104 weeks of age)
Table 8.	Comparison of gene frequency (F0, F2 and F6)

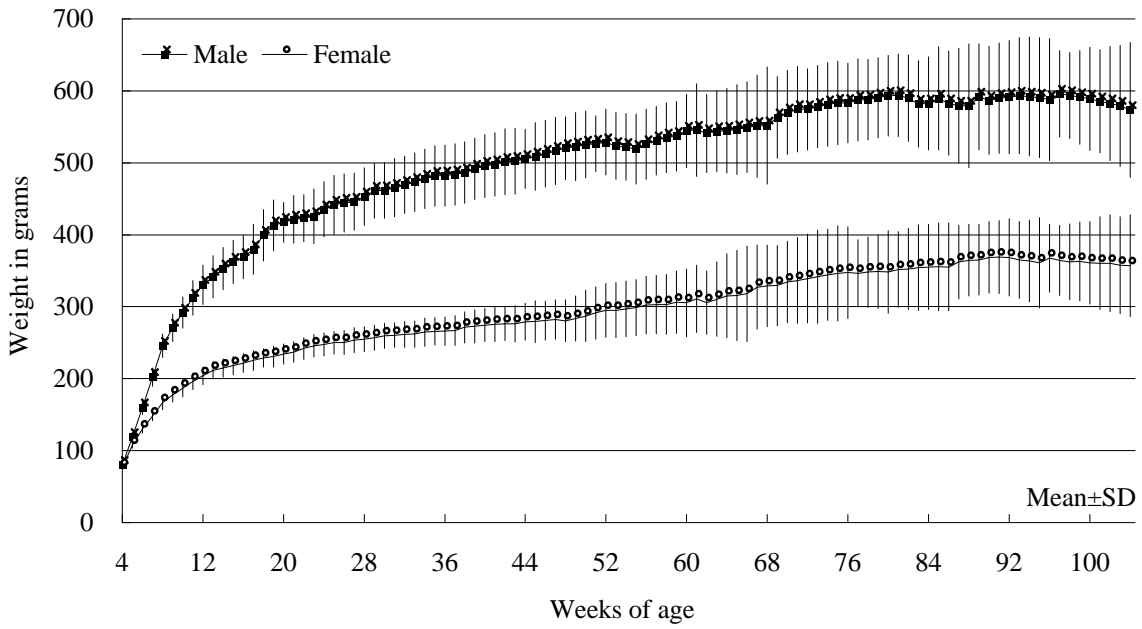


Figure 1. Body weight curve

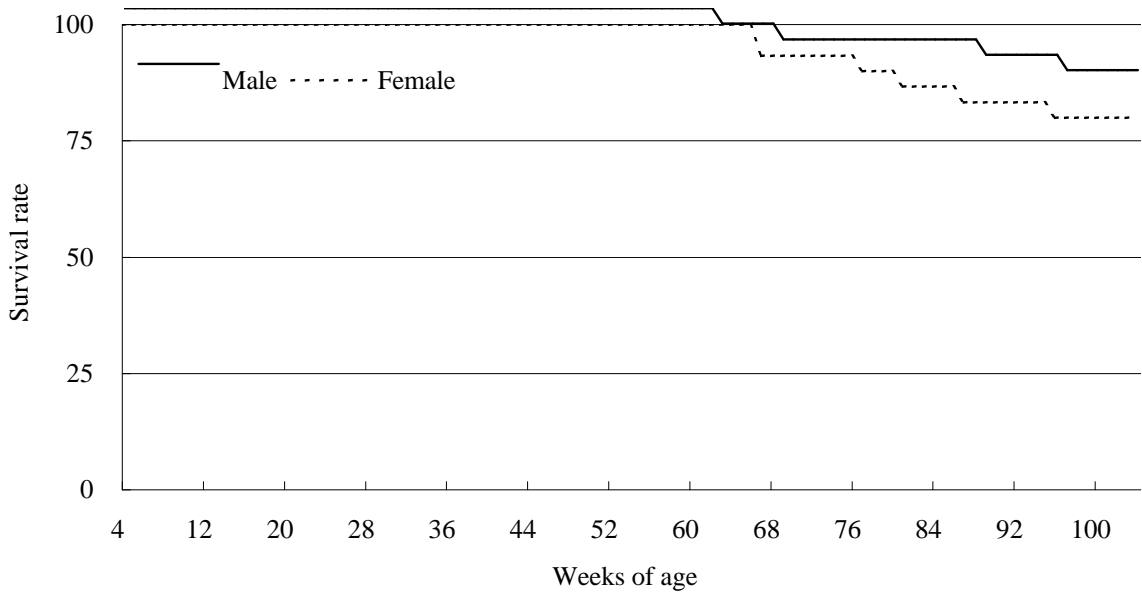


Figure 2. Survival rate curve



Table 1. Body weight

\*Data collection period : 5-Jul-99 to 6-Jun-01

\*Housing : group (3 to 5 weeks of age;10 heads/cage, 6 weeks of age and over;5 heads/cage)

Weeks	Unit :g						Weeks	Unit :g					
	Male			Female				Male			Female		
	n	Mean	SD	n	Mean	SD		n	Mean	SD	n	Mean	SD
4	30	79.9	4.8	30	76.5	2.7	53	30	523.3	46.3	30	295.1	38.3
5	30	118.9	6.8	30	107.3	4.0	54	30	522	46.5	30	296.8	38.7
6	30	160.2	10.0	30	130.0	6.2	55	30	519.3	48.7	30	298.8	39.0
7	30	202.2	12.9	30	148.4	6.9	56	30	526.1	48.7	30	302.3	40.3
8	30	245.9	16.6	30	166.9	9.8	57	30	531.0	47.8	30	302.7	40.7
9	30	270.7	18.8	30	177.6	10.3	58	30	535.0	48.4	30	303.2	42.0
10	30	291.8	21.5	30	186.7	12.0	59	30	536.9	48.5	30	306.1	43.3
11	30	312.1	24.1	30	196.4	11.4	60	30	544.4	51.1	30	305.5	47.2
12	30	330.3	27.6	30	203.9	12.1	61	30	545.7	64.5	30	311.1	46.5
13	30	341.8	29.4	30	211.8	12.3	62	30	541.1	54.4	30	305.9	44.1
14	30	353.0	29.5	30	214.8	12.7	63	29	544.0	55.9	30	310.5	51.9
15	30	362.4	29.8	30	218.1	12.5	64	29	544.6	59.0	30	315.2	58.3
16	30	369.2	30.0	30	221.6	13.0	65	29	546.2	62.6	30	315.8	62.6
17	30	379.6	34.7	30	225.2	13.5	66	29	549.4	62.8	30	318.1	66.2
18	30	399.6	35.7	30	228.9	12.8	67	29	550.9	70.8	29	327.2	58.2
19	30	413.0	35.3	30	230.7	14.2	68	29	551.8	81.3	29	329.2	56.7
20	30	417.4	27.7	30	234.1	14.1	69	28	563.3	56.8	29	329.4	55.6
21	30	421.3	32.8	30	237.1	14.4	70	28	570.1	58.4	29	334.1	56.7
22	30	423.0	32.8	30	242.0	14.8	71	28	574.3	59.3	29	336.6	59.8
23	30	425.8	38.3	30	245.6	15.7	72	28	574.2	56.6	29	339.2	61.8
24	30	435.2	38.4	30	247.7	15.9	73	28	578.1	57.0	29	341.5	64.9
25	30	441.6	41.2	30	249.9	16.0	74	28	581.0	58.1	29	344.6	63.4
26	30	444.3	40.4	30	250.3	16.8	75	28	583.0	58.2	29	346.3	65.9
27	30	446.1	39.8	30	253.8	17.4	76	28	583.4	55.4	29	347.3	63.7
28	30	453.0	39.8	30	255.2	17.4	77	28	587.5	56.9	27	346.4	46.9
29	30	460.8	38.1	30	256.8	17.3	78	28	588.2	56.0	27	348.1	49.3
30	30	461.7	38.8	30	259.5	17.4	79	28	590.3	56.0	27	348.8	51.1
31	30	465.3	40.3	30	260.4	17.0	80	28	593.1	56.0	27	348.5	57.4
32	30	469.3	39.6	30	261.5	18.3	81	28	593.6	57.4	26	351.7	52.6
33	30	473.2	40.5	30	262.0	18.3	82	28	590.2	60.0	26	352.6	56.3
34	30	478.0	41.3	30	264.7	19.7	83	28	581.9	60.1	26	354.1	59.3
35	30	482.0	42.1	30	265.8	19.1	84	28	582.3	64.7	26	355.1	58.9
36	30	482.1	42.7	30	266.0	19.7	85	28	589.5	71.8	26	355.4	61.0
37	30	483.7	42.7	30	266.8	20.6	86	28	582.8	72.6	26	355.2	61.0
38	30	486.7	42.6	30	271.3	21.4	87	28	579.5	79.9	25	362.2	51.2
39	30	491.9	42.9	30	272.6	23.2	88	28	579.5	86.1	25	364.6	49.7
40	30	495.6	43.9	30	274.4	23.0	89	27	591.6	74.0	25	365.2	49.1
41	30	498.0	44.0	30	275.3	23.8	90	27	586.9	75.3	25	368.6	49.7
42	30	501.4	45.5	30	276.2	23.3	91	27	589.9	77.0	25	368.8	50.6
43	30	502.3	45.6	30	276.2	25.5	92	27	591.4	78.9	25	368.6	53.6
44	30	505.3	41.1	30	279.1	25.8	93	27	593.1	80.9	25	365.1	53.6
45	30	508.7	47.3	30	279.3	29.1	94	27	592.2	82.3	25	363.7	56.6
46	30	512.7	46.3	30	280.7	27.3	95	27	590.3	83.5	25	361.0	62.5
47	30	516.6	46.7	30	282.3	27.4	96	27	587.8	85.0	24	367.5	47.2
48	30	520.3	43.7	30	280.6	28.8	97	26	596.0	60.1	24	364.5	48.8
49	30	522.6	47.3	30	283.4	31.3	98	26	593.6	59.9	24	362.4	52.8
50	30	525.3	46.2	30	287.2	35.7	99	26	591.2	65.0	24	363.0	54.6
51	30	526.4	38.6	30	291.4	36.3	100	26	589.0	71.9	24	361.1	57.6
52	30	528.6	45.7	30	295.0	37.4	101	26	585.3	71.7	24	360.5	64.5
							102	26	582.6	79.2	24	360.5	67.6
							103	26	579.3	84.0	24	357.8	67.5
							104	26	573.4	93.9	24	357.1	70.7

Table 2. Survival rate

\*Data collection period : 5-Jul-99 to 6-Jun-01

\*Housing : group (3 to 5 weeks of age;10 heads/cage, 6 weeks of age and over;5 heads/cage)

Weeks	Male		Female		Weeks	Male		Female	
	n	%	n	%		n	%	n	%
4	30	100.0	30	100.0	53	30	100.0	30	100.0
5	30	100.0	30	100.0	54	30	100.0	30	100.0
6	30	100.0	30	100.0	55	30	100.0	30	100.0
7	30	100.0	30	100.0	56	30	100.0	30	100.0
8	30	100.0	30	100.0	57	30	100.0	30	100.0
9	30	100.0	30	100.0	58	30	100.0	30	100.0
10	30	100.0	30	100.0	59	30	100.0	30	100.0
11	30	100.0	30	100.0	60	30	100.0	30	100.0
12	30	100.0	30	100.0	61	30	100.0	30	100.0
13	30	100.0	30	100.0	62	30	100.0	30	100.0
14	30	100.0	30	100.0	63	29	96.7	30	100.0
15	30	100.0	30	100.0	64	29	96.7	30	100.0
16	30	100.0	30	100.0	65	29	96.7	30	100.0
17	30	100.0	30	100.0	66	29	96.7	30	100.0
18	30	100.0	30	100.0	67	29	96.7	29	93.3
19	30	100.0	30	100.0	68	29	96.7	29	93.3
20	30	100.0	30	100.0	69	28	93.3	29	93.3
21	30	100.0	30	100.0	70	28	93.3	29	93.3
22	30	100.0	30	100.0	71	28	93.3	29	93.3
23	30	100.0	30	100.0	72	28	93.3	29	93.3
24	30	100.0	30	100.0	73	28	93.3	29	93.3
25	30	100.0	30	100.0	74	28	93.3	29	93.3
26	30	100.0	30	100.0	75	28	93.3	29	93.3
27	30	100.0	30	100.0	76	28	93.3	29	93.3
28	30	100.0	30	100.0	77	28	93.3	27	90.0
29	30	100.0	30	100.0	78	28	93.3	27	90.0
30	30	100.0	30	100.0	79	28	93.3	27	90.0
31	30	100.0	30	100.0	80	28	93.3	27	90.0
32	30	100.0	30	100.0	81	28	93.3	26	86.7
33	30	100.0	30	100.0	82	28	93.3	26	86.7
34	30	100.0	30	100.0	83	28	93.3	26	86.7
35	30	100.0	30	100.0	84	28	93.3	26	86.7
36	30	100.0	30	100.0	85	28	93.3	26	86.7
37	30	100.0	30	100.0	86	28	93.3	26	86.7
38	30	100.0	30	100.0	87	28	93.3	25	83.3
39	30	100.0	30	100.0	88	28	93.3	25	83.3
40	30	100.0	30	100.0	89	27	90.0	25	83.3
41	30	100.0	30	100.0	90	27	90.0	25	83.3
42	30	100.0	30	100.0	91	27	90.0	25	83.3
43	30	100.0	30	100.0	92	27	90.0	25	83.3
44	30	100.0	30	100.0	93	27	90.0	25	83.3
45	30	100.0	30	100.0	94	27	90.0	25	83.3
46	30	100.0	30	100.0	95	27	90.0	25	83.3
47	30	100.0	30	100.0	96	27	90.0	24	80.0
48	30	100.0	30	100.0	97	26	86.7	24	80.0
49	30	100.0	30	100.0	98	26	86.7	24	80.0
50	30	100.0	30	100.0	99	26	86.7	24	80.0
51	30	100.0	30	100.0	100	26	86.7	24	80.0
52	30	100.0	30	100.0	101	26	86.7	24	80.0
					102	26	86.7	24	80.0
					103	26	86.7	24	80.0
					104	26	86.7	24	80.0

Table 3. Hematology

\*Data collection period : 15-Sep-99 to 6-Jun-01

\*Blood samples were drawn from the retro-orbital plexus using a micro-hematocrit glass capillary tube treated with EDTA.

\*Method : Sysmex (TOA) F-800 Multi-parameter automated hematology analyzer

Items	Unit	5 weeks						10 weeks					
		Male			Female			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
RBC	( $10^{12}/l$ )	10	6.29	0.26	10	6.26	0.24	10	9.03	0.27	10	8.19	0.24
Hgb	(g/l)	10	132	6	10	132	4	10	169	5	10	159	4
Hct	(l)	10	0.426	0.035	10	0.406	0.014	10	0.527	0.017	10	0.483	0.024
MCV	(fl)	10	67.6	3.4	10	64.9	2.3	10	58.5	0.8	10	59.0	1.8
MCH	(pg)	10	21.0	0.6	10	21.1	0.7	10	18.7	0.4	10	19.4	0.5
MCHC	(g/l)	10	311	13	10	326	3	10	320	7	10	330	13
WBC	( $\times 10^9/l$ )	10	6.3	1.4	10	5.6	1.1	10	7.5	2.1	10	6.6	0.9
Plat.	( $\times 10^9/l$ )	10	1214	151	10	1097	174	10	992	109	10	1010	113
RDW	(fl)	10	35.2	1.6	10	32.4	2.2	10	27.1	0.9	10	25.7	0.8
PDW	(fl)	10	7.6	0.3	10	7.7	0.3	10	8.5	0.4	10	8.6	0.6
MPV	(fl)	10	7.5	0.2	10	7.5	0.2	10	8.0	0.3	10	8.1	0.3

Items	Unit	18 weeks						31 weeks					
		Male			Female			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
RBC	( $10^{12}/l$ )	10	9.83	0.45	10	8.74	0.25	10	10.16	0.51	10	9.10	0.46
Hgb	(g/l)	10	169	6	10	163	4	10	172	3	10	166	5
Hct	(l)	10	0.531	0.023	10	0.497	0.014	10	0.545	0.020	10	0.519	0.022
MCV	(fl)	10	54.1	1.5	10	56.9	1.1	10	53.7	1.5	10	57.1	1.9
MCH	(pg)	10	17.2	0.5	10	18.6	0.4	10	16.9	0.8	10	18.3	0.9
MCHC	(g/l)	10	319	7	10	327	5	10	315	12	10	320	9
WBC	( $\times 10^9/l$ )	10	8.0	1.9	10	7.0	1.6	10	7.7	2.6	10	4.9	0.4
Plat.	( $\times 10^9/l$ )	10	975	88	10	1025	139	10	941	80	10	1001	110
RDW	(fl)	10	25.6	0.6	10	24.6	0.6	10	25.8	0.5	10	25.4	0.6
PDW	(fl)	10	8.3	0.2	10	8.3	0.6	10	7.9	0.5	10	7.7	0.3
MPV	(fl)	10	7.9	0.1	10	8.0	0.4	10	7.7	0.3	10	7.6	0.2

Items	Unit	52 weeks						104 weeks					
		Male			Female			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
RBC	( $10^{12}/l$ )	10	10.27	0.41	10	8.35	0.25	10	9.62	0.46	10	8.62	0.43
Hgb	(g/l)	10	176	5	10	162	5	10	166	7	10	161	6
Hct	(l)	10	0.564	0.020	10	0.507	0.016	10	0.520	0.022	10	0.512	0.018
MCV	(fl)	10	55.0	2.5	10	60.7	1.4	10	54.1	2.3	10	59.5	1.1
MCH	(pg)	10	17.1	0.5	10	19.5	0.5	10	17.3	0.8	10	18.7	0.5
MCHC	(g/l)	10	312	15	10	321	7	10	319	5	10	314	7
WBC	( $\times 10^9/l$ )	10	5.9	0.9	10	4.5	1.2	10	7.9	2.0	10	3.9	0.7
Plat.	( $\times 10^9/l$ )	10	929	115	10	849	87	10	955	139	10	960	93
RDW	(fl)	10	25.8	1.0	10	26.7	0.6	10	26.4	1.1	10	26.8	0.7
PDW	(fl)	10	8.6	0.4	10	8.1	0.3	8	9.1	0.9	0	- <sup>¶</sup>	0.0
MPV	(fl)	10	7.8	0.2	10	7.8	0.2	8	8.1	0.3	0	- <sup>¶</sup>	0.0

<sup>¶</sup> Analysis error

Table 4-1. Clinical biochemistry

\*Data collection period : 21-Oct-99 to 8-Jun-01

\*Blood samples were drawn from the abdominal aorta after 24 hours fasting period.

\*Method : GPT, GOT, ALP, LDH, LAP, ChE, CPK, Glucose, TC, PL, TG, NEFA, Ca, IP, Bilirubin, BUN, Creatinine and TP ; Discrete type auto analyzer COBAS<sup>®</sup> MIRA, Nippon Roche K.K. Na and K ; Flame photometry MF-303, JASCO Corp. Cl ; Chloridometer CL-12, JASCO Corp. A/G, Albumin, a1-G, a2-G, β-G and ?-G ; Electrophoresis apparatus LP-225, Densitometer D-607, Cosmo co.,Ltd.

Items	Unit	5 weeks						10 weeks					
		Male			Female			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
GPT	(U/l)	10	39.0	6.4	10	32.0	7.0	10	40.2	5.3	10	32.3	8.9
GOT <sup>‡</sup>	(U/l)	10	89.4	15.3	10	86.3	12.6	10	75.9	14.4	10	83.7	40.6
ALP	(U/l)	10	279.8	48.9	10	222.7	24.4	10	154.8	31.1	10	84.8	14.7
LDH <sup>‡</sup>	(U/l)	10	118.7	29.4	10	112.7	23.7	10	94.8	23.5	10	100.5	18.7
LAP	(U/l)	10	76.9	3.2	10	76.0	5.9	10	75.9	5.9	10	68.3	6.1
ChE	(IU/l)	10	53.0	9.6	10	74.4	20.1	2 <sup>¶</sup>	38.0	42.4	10	159.6	71.4
CPK <sup>‡</sup>	(U/l)	10	327.5	66.8	10	268.3	57.8	10	153.1	26.2	10	114.3	26.9
Glucose <sup>‡</sup>	(mmol/l)	10	6.3	1.1	10	5.3	0.5	10	8.8	1.6	10	6.9	1.1
TC	(mmol/l)	10	1.42	0.14	10	1.37	0.12	10	1.09	0.14	10	0.87	0.22
PL	(mmol/l)	10	2.21	0.17	10	2.31	0.25	10	1.96	0.16	10	2.14	0.44
TG	(mmol/l)	10	1.41	0.26	10	1.28	0.34	10	1.16	0.29	10	0.62	0.15
NEFA	(mmol/l)	10	1.22	0.30	10	1.12	0.16	10	0.74	0.15	10	0.71	0.13
Ca	(mmol/l)	10	2.57	0.11	10	2.62	0.09	10	2.77	0.20	10	2.74	0.11
Na	(mmol/l)	10	133	2	10	134	2	10	138	2	10	137	3
K	(mmol/l)	10	4.5	0.3	10	4.5	0.2	10	4.3	0.3	10	3.9	0.3
Cl	(mmol/l)	10	103	2	10	105	2	10	105	1	10	107	2
IP	(mmol/l)	10	3.20	0.25	10	3.20	0.31	10	2.70	0.16	10	2.54	0.34
Bilirubin	(μmol/l)	10	1.97	0.45	10	1.30	0.35	10	0.84	0.33	9	0.93	0.36
BUN	(mmol/l)	10	9.12	1.39	10	8.77	1.41	10	9.44	0.69	10	9.05	1.03
Creatinine	(μmol/l)	10	39.9	3.5	10	39.7	3.0	10	55.0	2.9	10	55.6	5.1
TP	(g/l)	10	58.5	2.2	10	58.7	2.2	10	71.3	5.5	10	73.5	6.1
A/G		10	1.55	0.08	10	1.59	0.14	10	1.20	0.07	10	1.22	0.08
Albumin	(%)	10	60.84	1.25	10	60.72	2.63	10	54.52	1.34	10	54.80	1.72
a1-G	(%)	10	16.56	0.72	10	15.62	0.93	10	20.39	1.45	10	19.88	1.20
a2-G	(%)	10	6.32	1.04	10	5.92	1.19	10	7.56	0.67	10	6.43	0.68
β-G	(%)	10	13.75	1.18	10	14.17	1.56	10	14.54	0.56	10	15.05	1.22
?-G	(%)	10	2.53	0.82	10	3.57	2.05	10	2.99	0.42	10	3.84	0.89
Albumin	(g/l)	10	35.3	1.2	10	35.3	2.3	10	38.9	3.1	10	40.3	3.9
a1-G	(g/l)	10	9.6	0.5	10	9.1	0.8	10	14.5	1.0	10	14.6	1.7
a2-G	(g/l)	10	3.7	0.6	10	3.4	0.7	10	5.4	0.9	10	4.7	0.6
β-G	(g/l)	10	8.0	0.8	10	8.2	0.9	10	10.4	1.0	10	11.1	1.3
?-G	(g/l)	10	1.5	0.5	10	2.1	1.1	10	2.1	0.4	10	2.8	0.4

<sup>‡</sup> Heparinized plasma.<sup>¶</sup> 8/10 samples were analysis error.

Table 4-2. Clinical biochemistry

\*Data collection period : 21-Oct-99 to 16-Jun-00

\*Blood samples were drawn from the abdominal aorta after 24 hours fasting period.

\*Method : GPT, GOT, ALP, LDH, LAP, ChE, CPK, Glucose, TC, PL, TG, NEFA, Ca, IP, Bilirubin, BUN, Creatinine and TP ; Discrete type auto analyzer COBAS® MIRA, Nippon Roche K.K. Na and K ; Flame photometry MF-303, JASCO Corp. Cl ; Chloridometer CL-12, JASCO Corp. A/G, Albumin, a1-G, a2-G, β-G and ?-G ; Electrophoresis apparatus LP-225, Densitometer D-607, Cosmo co.,Ltd.

Items	Unit	18 weeks						31 weeks					
		Male			Female			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
GPT	(U/l)	10	38.7	5.6	10	31.4	5.8	10	44.5	6.7	10	43.0	19.8
GOT ‡	(U/l)	10	74.8	10.0	10	77.6	17.9	10	65.7	9.4	10	69.9	27.0
ALP	(U/l)	10	108.7	25.7	10	38.3	7.7	10	94.4	18.8	10	28.7	7.9
LDH ‡	(U/l)	10	113.2	18.9	10	146.8	80.9	10	124.2	42.3	10	163.1	171.6
LAP	(U/l)	10	76.5	7.5	10	60.6	5.7	10	65.0	5.7	10	56.2	5.8
ChE	(IU/l)	10	18.4	5.3	10	408.3	94.3	10	36.3	21.3	10	590.0	147.5
CPK ‡	(U/l)	10	105.0	17.1	10	155.6	177.5	10	124.1	36.9	10	101.2	68.2
Glucose ‡	(mmol/l)	10	10.1	1.0	10	7.1	0.8	10	7.7	0.9	10	6.4	0.6
TC	(mmol/l)	10	1.33	0.33	10	1.04	0.24	10	1.49	0.15	10	1.36	0.29
PL	(mmol/l)	10	2.46	0.52	10	2.33	0.41	10	2.40	0.24	10	2.66	0.49
TG	(mmol/l)	10	1.42	0.57	10	0.68	0.21	10	1.41	0.46	10	0.63	0.14
NEFA	(mmol/l)	10	0.72	0.19	10	0.79	0.19	10	0.69	0.15	10	0.78	0.08
Ca	(mmol/l)	10	2.77	0.08	10	2.59	0.08	10	2.86	0.15	10	2.80	0.16
Na	(mmol/l)	10	142	2	10	140	3	10	142	7	10	142	4
K	(mmol/l)	10	4.4	0.3	10	4.1	0.3	10	4.4	0.3	10	3.8	0.3
Cl	(mmol/l)	10	104	1	10	106	2	10	102	4	10	103	3
IP	(mmol/l)	10	2.06	0.30	10	2.06	0.20	10	1.85	0.30	10	1.83	0.41
Bilirubin	(μmol/l)	10	1.83	0.48	10	2.09	0.59	10	1.03	0.27	10	1.28	0.44
BUN	(mmol/l)	10	8.19	1.15	10	7.73	0.67	10	8.08	0.94	10	8.68	0.84
Creatinine	(μmol/l)	10	61.1	4.4	10	56.0	3.8	10	61.3	5.8	10	58.9	4.8
TP	(g/l)	10	78.8	5.3	10	74.8	3.8	10	75.7	4.6	10	73.5	7.7
A/G		10	1.05	0.05	10	1.18	0.06	10	0.95	0.05	10	1.18	0.09
Albumin	(%)	10	51.15	1.28	10	54.14	1.29	10	48.81	1.36	10	54.09	1.87
a1-G	(%)	10	19.33	0.98	10	18.73	1.12	10	21.40	1.54	10	18.66	1.43
a2-G	(%)	10	7.30	1.33	10	5.82	0.55	10	6.64	1.39	10	5.04	1.29
β-G	(%)	10	17.10	0.39	10	14.69	0.97	10	18.79	0.71	10	15.52	1.43
?-G	(%)	10	5.12	0.52	10	6.62	0.77	10	4.44	0.83	10	6.69	0.97
Albumin	(g/l)	10	40.3	2.6	10	40.5	2.5	10	36.9	2.3	10	39.8	4.4
a1-G	(g/l)	10	15.3	1.7	10	14.0	1.3	10	16.2	1.3	10	13.8	2.0
a2-G	(g/l)	10	5.7	1.0	10	4.3	0.4	10	5.1	1.3	10	3.7	1.1
β-G	(g/l)	10	13.5	1.1	10	11.0	0.6	10	14.2	0.9	10	11.4	1.4
?-G	(g/l)	10	4.0	0.6	10	4.9	0.6	10	3.4	0.7	10	4.9	0.7

‡ Heparinized plasma.

Table 4-3. Clinical biochemistry

\*Data collection period : 21-Oct-99 to 16-Jun-00

\*Blood samples were drawn from the abdominal aorta after 24 hours fasting period.

\*Method : GPT, GOT, ALP, LDH, LAP, ChE, CPK, Glucose, TC, PL, TG, NEFA, Ca, IP, Bilirubin, BUN, Creatinine and TP ; Discrete type auto analyzer COBAS<sup>®</sup> MIRA, Nippon Roche K.K. Na and K ; Flame photometry MF-303, JASCO Corp. Cl ; Chloridometer CL-12, JASCO Corp. A/G, Albumin, a1-G, a2-G, β-G and ?-G ; Electrophoresis apparatus LP-225, Densitometer D-607, Cosmo co.,Ltd.

Items	Unit	52 weeks						104 weeks					
		Male			Female			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
GPT	(U/l)	10	81.74 <sup>¶</sup>	125.4	10	33.7	8.5	10	44.7	17.4	10	45.7	18.0
GOT <sup>‡</sup>	(U/l)	10	123.3 <sup>¶</sup>	150.7	10	64.7	10.6	10	63.4	19.8	10	81.6	24.1
ALP	(U/l)	10	76.7	21.8	10	24.3	7.6	10	75.8	24.4	10	19.2	6.7
LDH <sup>‡</sup>	(U/l)	10	265.1 <sup>¶</sup>	230.8	10	139.5	50.3	10	144.5	62.0	10	122.7	41.4
LAP	(U/l)	10	69.7	9.5	10	54.7	5.8	10	71.1	6.0	10	48.2	4.1
ChE	(IU/l)	10	65.7	20.9	10	536.1	105.4	10	100.7	81.9	10	357.6	117.7
CPK <sup>‡</sup>	(U/l)	10	118.3	28.0	10	80.1	12.4	10	206.1	74.5	10	104.1	37.4
Glucose <sup>‡</sup>	(mmol/l)	10	6.6	0.8	10	5.1	0.8	10	7.4	0.8	10	6.1	0.9
TC	(mmol/l)	10	1.59	0.55	10	1.22	0.32	10	2.56	0.80	10	1.16	0.31
PL	(mmol/l)	10	2.18	0.79	10	2.47	0.62	10	4.54	0.80	10	2.68	0.68
TG	(mmol/l)	10	1.26	0.38	10	0.62	0.19	10	3.37	1.62	10	0.97	0.51
NEFA	(mmol/l)	10	0.75	0.10	10	0.76	0.21	10	0.61	0.17	10	0.83	0.11
Ca	(mmol/l)	10	2.78	0.19	10	2.87	0.14	10	3.04	0.23	10	2.63	0.15
Na	(mmol/l)	10	138	6	10	135	3	10	131	3	10	135	4
K	(mmol/l)	10	4.3	0.3	10	4.0	0.9	10	3.9	0.3	10	3.8	0.4
Cl	(mmol/l)	10	101	2	10	103	3	10	97	2	10	100	3
IP	(mmol/l)	10	1.54	0.23	10	1.67	0.40	10	1.76	0.26	10	1.49	0.24
Bilirubin	(μmol/l)	10	1.57	0.98	10	2.00	0.49	10	1.64	0.46	10	2.34	0.48
BUN	(mmol/l)	10	6.18	0.87	10	7.35	1.16	10	7.23	1.13	10	5.50	0.80
Creatinine	(μmol/l)	10	63.1	6.9	10	64.2	4.7	10	72.8	10.5	10	57.5	4.3
TP	(g/l)	10	72.6	5.7	10	74.8	4.0	10	80.1	7.3	10	71.9	5.0
A/G		10	0.91	0.08	10	1.20	0.11	10	0.80	0.11	10	1.13	0.12
Albumin	(%)	10	47.61	2.03	10	54.49	2.44	10	44.24	3.51	10	52.83	2.75
a1-G	(%)	10	20.92	1.20	10	18.24	1.43	10	24.64	4.95	10	17.10	1.43
a2-G	(%)	10	7.09	1.22	10	4.76	0.37	10	7.40	0.94	10	6.50	0.85
β-G	(%)	10	18.96	1.07	10	15.73	1.12	10	18.89	3.62	10	16.39	1.85
?-G	(%)	10	5.42	0.85	10	6.78	0.76	10	4.83	1.39	10	7.18	1.75
Albumin	(g/l)	10	34.5	2.9	10	40.8	2.7	10	35.4	4.4	10	37.9	2.9
a1-G	(g/l)	10	15.2	1.6	10	13.6	1.3	10	19.7	4.1	10	12.3	1.4
a2-G	(g/l)	10	5.1	0.9	10	3.6	0.2	10	5.9	0.8	10	4.7	0.8
β-G	(g/l)	10	13.8	1.3	10	11.8	1.2	10	15.1	3.3	10	11.8	1.9
?-G	(g/l)	10	3.9	0.8	10	5.1	0.7	10	3.9	1.3	10	5.1	1.2

<sup>‡</sup> Heparinized plasma.<sup>¶</sup> 1/10 sample had abnormal high value.

Table 5-1. Urinalysis

\*Data collection period : 14-Sep-99 to 6-Jun-01

\*Method : Urin test strip (URIACE(R)-M), Terumo Corp.

Items		5 weeks		10 weeks		18 weeks	
		Male n=10 %	Female n=10 %	Male n=10 %	Female n=10 %	Male n=10 %	Female n=10 %
pH	5	10	0	0	10	0	10
	6	10	20	0	10	20	50
	7	80	70	70	50	50	40
	8	0	10	30	30	30	0
	9	0	0	0	0	0	0
Glucose <sup>‡1</sup>	-	100	100	100	100	100	100
	±	0	0	0	0	0	0
	+	0	0	0	0	0	0
	++	0	0	0	0	0	0
	+++	0	0	0	0	0	0
Protein <sup>‡2</sup>	-	0	20	0	0	0	10
	±	90	70	60	50	60	90
	+	10	10	40	50	30	0
	++	0	0	0	0	10	0
	+++	0	0	0	0	0	0
Urobilinogen <sup>‡3</sup>	±	10	30	20	60	70	70
	+	90	70	80	40	30	30
	++	0	0	0	0	0	0
	+++	0	0	0	0	0	0
Bilirubin <sup>‡4</sup>	-	100	100	100	100	100	100
	+	0	0	0	0	0	0
	++	0	0	0	0	0	0
	+++	0	0	0	0	0	0
Ketone body <sup>‡5</sup>	-	100	100	80	100	50	70
	+	0	0	20	0	50	30
	++	0	0	0	0	0	0
	+++	0	0	0	0	0	0
Occult blood <sup>‡6</sup>	-	90	70	80	80	60	100
	+	10	30	20	20	30	0
	++	0	0	0	0	10	0
	+++	0	0	0	0	0	0

<sup>‡1</sup> ± 50mg/dl, + 150mg/dl, ++ 500mg/dl, +++ 2000mg/dl<sup>‡2</sup> ± 15mg/dl, + 30mg/dl, ++ 100mg/dl, +++ 250mg/dl<sup>‡3</sup> ± 0.5mg/dl, + 2mg/dl, ++ 4mg/dl, +++ 8mg/dl<sup>‡4</sup> + 0.5mg/dl, ++ 1.0mg/dl, +++ 2.5mg/dl<sup>‡5</sup> + 10mg/dl, ++ 50mg/dl, +++ 100mg/dl<sup>‡6</sup> + 10RBC/μl, ++ 50RBC/μl, +++ 250RBC/μl

Table 5-2. Urinalysis

\*Data collection period : 14-Sep-99 to 13-Jun-00

\*Method : Urin test strip (URIACE(R)-M), Terumo Corp.

Items		31 weeks		52 weeks		104 weeks	
		Male n=10 %	Female n=10 %	Male n=10 %	Female n=10 %	Male n=10 %	Female n=10 %
pH	5	0	0	10	0	0	0
	6	30	30	0	60	30	60
	7	50	70	70	40	50	30
	8	20	0	20	0	20	10
	9	0	0	0	0	0	0
Glucose <sup>‡1</sup>	-	100	100	100	100	100	100
	±	0	0	0	0	0	0
	+	0	0	0	0	0	0
	++	0	0	0	0	0	0
	+++	0	0	0	0	0	0
Protein <sup>‡2</sup>	-	0	10	0	0	0	0
	±	40	50	70	10	0	20
	+	40	40	30	80	0	30
	++	20	0	0	10	10	20
	+++	0	0	0	0	90	30
Urobilinogen <sup>‡3</sup>	±	100	70	80	60	80	100
	+	0	30	20	40	20	0
	++	0	0	0	0	0	0
	+++	0	0	0	0	0	0
Bilirubin <sup>‡4</sup>	-	100	100	100	100	100	100
	+	0	0	0	0	0	0
	++	0	0	0	0	0	0
	+++	0	0	0	0	0	0
Ketone body <sup>‡5</sup>	-	50	60	90	10	30	40
	+	50	40	10	90	70	60
	++	0	0	0	0	0	0
	+++	0	0	0	0	0	0
Occult blood <sup>‡6</sup>	-	90	100	80	60	90	70
	+	10	0	20	40	0	0
	++	0	0	0	0	0	0
	+++	0	0	0	0	10	30

<sup>‡1</sup> ± 50mg/dl, + 150mg/dl, ++ 500mg/dl, +++ 2000mg/dl<sup>‡2</sup> ± 15mg/dl, + 30mg/dl, ++ 100mg/dl, +++ 250mg/dl<sup>‡3</sup> ± 0.5mg/dl, + 2mg/dl, ++ 4mg/dl, +++ 8mg/dl<sup>‡4</sup> + 0.5mg/dl, ++ 1.0mg/dl, +++ 2.5mg/dl<sup>‡5</sup> + 10mg/dl, ++ 50mg/dl, +++ 100mg/dl<sup>‡6</sup> + 10RBC/μl, ++ 50RBC/μl, +++ 250RBC/μl



Table 6-1. Absolute and relative organ weight

\*Data collection period : 17-Sep-99 to 8-Jun-01

\*Method : B.W. and organ weight measurement were performed after 24-hour fasting period.

	Unit	5 weeks						10 weeks					
		Male			Female			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Body weight	(g)	10	109.3	6.44	10	94.6	6.57	10	283.7	11.26	10	174.5	11.66
Absolute organ weight													
Brain	(mg)	10	1619	96	10	1568	132	10	1894	94	10	1778	138
Pituitary gland	(mg)	10	4.2	0.7	10	4.7	0.7	10	8.4	1.9	10	10.5	2.3
Heart	(mg)	10	437.2	38.0	10	373.0	36.6	10	862.6	84.7	10	544.6	51.3
Lung	(mg)	10	597.8	26.8	10	524.4	32.8	10	1009.8	76.1	10	778.7	89.6
Stomach	(mg)	10	745.5	65.3	10	701.0	80.4	10	1374.6	175.9	10	1021.2	171.4
Liver	(mg)	10	3820	256	10	3326	467	10	8051	508	10	5159	531
Spleen	(mg)	10	383.2	37.6	10	296.9	57.4	10	658.4	123.1	10	421.5	41.6
Kidney(R)	(mg)	10	531.5	59.3	10	461.0	40.3	10	1024.4	161.1	10	691.8	85.6
Kidney(L)	(mg)	10	522.4	33.7	10	451.0	28.8	10	989.7	129.2	10	661.2	71.6
Kidneys	(mg)	10	1053.9	87.2	10	912.0	68.1	10	2014.1	281.9	10	1353.1	153.7
Adrenal(R)	(mg)	10	15.7	3.2	10	15.1	3.8	10	28.0	5.0	10	33.2	4.4
Adrenal(L)	(mg)	10	18.2	2.8	10	16.2	2.9	10	30.2	3.0	10	36.7	5.1
Adrenals	(mg)	10	33.9	5.3	10	31.2	5.9	10	58.3	7.6	10	69.9	9.0
Seminal vesicle	(mg)	10	38.4	9.3	-	-	-	10	507.5	104.4	-	-	-
Uterus	(mg)	-	-	-	10	157.9	68.1	-	-	-	10	395.5	99.6
Testis(R)	(mg)	10	581.9	36.9	-	-	-	10	1574.3	120.6	-	-	-
Testis(L)	(mg)	10	602.3	40.6	-	-	-	10	1643.3	167.1	-	-	-
Ovary(R)	(mg)	-	-	-	10	21.9	3.4	-	-	-	10	52.7	11.8
Ovary(L)	(mg)	-	-	-	10	27.0	4.1	-	-	-	10	54.9	10.9
Urinary bladder	(mg)	10	51.7	5.2	10	43.7	7.8	10	85.6	22.0	10	61.2	10.2
Relative organ weight													
Brain	(%)	10	1.486	0.132	10	1.663	0.151	10	0.669	0.042	10	1.020	0.063
Pituitary gland	(%)	10	0.004	0.001	10	0.005	0.001	10	0.003	0.001	10	0.006	0.001
Heart	(%)	10	0.400	0.031	10	0.395	0.033	10	0.304	0.022	10	0.312	0.020
Lung	(%)	10	0.548	0.023	10	0.555	0.023	10	0.356	0.022	10	0.446	0.034
Stomach	(%)	10	0.684	0.073	10	0.741	0.065	10	0.485	0.061	10	0.583	0.073
Liver	(%)	10	3.495	0.130	10	3.518	0.432	10	2.839	0.165	10	2.952	0.181
Spleen	(%)	10	0.351	0.034	10	0.315	0.060	10	0.232	0.039	10	0.242	0.022
Kidney(R)	(%)	10	0.486	0.046	10	0.487	0.021	10	0.360	0.047	10	0.395	0.025
Kidney(L)	(%)	10	0.478	0.027	10	0.477	0.019	10	0.348	0.034	10	0.378	0.021
Kidneys	(%)	10	0.965	0.066	10	0.965	0.036	10	0.708	0.077	10	0.774	0.042
Adrenal(R)	(%)	10	0.014	0.003	10	0.016	0.004	10	0.010	0.002	10	0.019	0.002
Adrenal(L)	(%)	10	0.017	0.002	10	0.017	0.003	10	0.011	0.001	10	0.021	0.002
Adrenals	(%)	10	0.031	0.005	10	0.033	0.006	10	0.021	0.003	10	0.040	0.004
Seminal vesicle	(%)	10	0.035	0.008	-	-	-	10	0.178	0.031	-	-	-
Uterus	(%)	-	-	-	10	0.165	0.067	-	-	-	10	0.226	0.055
Testis(R)	(%)	10	0.534	0.039	-	-	-	10	0.555	0.038	-	-	-
Testis(L)	(%)	10	0.552	0.037	-	-	-	10	0.579	0.056	-	-	-
Ovary(R)	(%)	-	-	-	10	0.023	0.003	-	-	-	10	0.030	0.006
Ovary(L)	(%)	-	-	-	10	0.029	0.005	-	-	-	10	0.031	0.006
Urinary bladder	(%)	10	0.047	0.005	10	0.046	0.006	10	0.030	0.007	10	0.035	0.006

Table 6-2. Absolute and relative organ weight

\*Data collection period : 17-Sep-99 to 16-Jun-00

\*Method : B.W. and organ weight measurement were performed after 24-hour fasting period.

	Unit	18 weeks						31 weeks					
		Male			Female			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Body weight	(g)	10	383.5	24.03	10	220.9	16.04	10	442.0	41.98	10	236.0	15.21
Absolute organ weight													
Brain	(mg)	10	1896	136	10	1730	115	10	2070	156	10	1969	100
Pituitary gland	(mg)	10	9.7	1.0	10	12.6	3.5	10	8.8	1.4	10	14.1	4.3
Heart	(mg)	10	950.9	68.6	10	625.3	58.0	10	1044.4	130.4	10	682.9	39.7
Lung	(mg)	10	1075.7	62.7	10	844.8	48.9	10	1103.2	102.3	10	855.7	66.4
Stomach	(mg)	10	1585.7	228.7	10	1225.7	224.8	10	1768.1	246.7	10	1446.4	360.7
Liver	(mg)	10	9827	777	10	5299	599	10	10546	1369	10	5719	617
Spleen	(mg)	10	654.6	57.6	10	435.6	56.0	10	688.8	97.0	10	529.1	56.1
Kidney(R)	(mg)	10	1158.1	92.8	10	714.0	73.8	10	1187.6	129.7	10	757.6	77.4
Kidney(L)	(mg)	10	1103.7	103.3	10	678.2	77.5	10	1127.9	106.0	10	709.4	79.1
Kidneys	(mg)	10	2261.7	185.8	10	1392.2	145.7	10	2315.5	222.8	10	1467.0	153.2
Adrenal(R)	(mg)	10	27.5	3.4	10	32.7	5.2	10	24.8	2.7	10	31.2	5.1
Adrenal(L)	(mg)	10	30.1	3.9	10	37.8	6.7	10	29.4	4.1	10	33.6	4.7
Adrenals	(mg)	10	57.6	6.7	10	70.5	10.7	10	54.2	6.6	10	64.8	9.3
Seminal vesicle	(mg)	10	948.3	178.6	-	-	-	10	1049.1	234.8	-	-	-
Uterus	(mg)	-	-	-	10	471.3	117.3	-	-	-	10	630.1	303.1
Testis(R)	(mg)	10	1672.0	68.9	-	-	-	10	1731.8	146.3	-	-	-
Testis(L)	(mg)	10	1692.3	75.9	-	-	-	10	1752.8	156.8	-	-	-
Ovary(R)	(mg)	-	-	-	10	58.6	13.0	-	-	-	10	58.3	8.5
Ovary(L)	(mg)	-	-	-	10	57.7	12.4	-	-	-	10	56.5	10.6
Urinary bladder	(mg)	10	104.8	16.8	10	62.4	10.9	10	99.9	23.6	10	55.6	10.8
Relative organ weight													
Brain	(%)	10	0.496	0.039	10	0.785	0.056	10	0.472	0.053	10	0.836	0.053
Pituitary gland	(%)	10	0.003	0.000	10	0.006	0.001	10	0.002	0.000	10	0.006	0.002
Heart	(%)	10	0.248	0.016	10	0.283	0.022	10	0.236	0.019	10	0.290	0.011
Lung	(%)	10	0.281	0.018	10	0.383	0.018	10	0.250	0.012	10	0.362	0.010
Stomach	(%)	10	0.413	0.050	10	0.554	0.079	10	0.399	0.037	10	0.609	0.127
Liver	(%)	10	2.563	0.135	10	2.400	0.218	10	2.380	0.121	10	2.422	0.193
Spleen	(%)	10	0.171	0.013	10	0.197	0.020	10	0.157	0.023	10	0.225	0.028
Kidney(R)	(%)	10	0.302	0.019	10	0.323	0.015	10	0.269	0.021	10	0.321	0.021
Kidney(L)	(%)	10	0.288	0.021	10	0.306	0.018	10	0.255	0.013	10	0.300	0.022
Kidneys	(%)	10	0.590	0.036	10	0.629	0.028	10	0.525	0.030	10	0.621	0.041
Adrenal(R)	(%)	10	0.007	0.001	10	0.015	0.002	10	0.006	0.000	10	0.013	0.002
Adrenal(L)	(%)	10	0.008	0.001	10	0.017	0.002	10	0.007	0.001	10	0.014	0.001
Adrenals	(%)	10	0.015	0.003	10	0.032	0.003	10	0.012	0.001	10	0.027	0.003
Seminal vesicle	(%)	10	0.247	0.045	-	-	-	10	0.240	0.056	-	-	-
Uterus	(%)	-	-	-	10	0.215	0.057	-	-	-	10	0.265	0.119
Testis(R)	(%)	10	0.437	0.027	-	-	-	10	0.394	0.039	-	-	-
Testis(L)	(%)	10	0.442	0.027	-	-	-	10	0.399	0.039	-	-	-
Ovary(R)	(%)	-	-	-	10	0.027	0.006	-	-	-	10	0.025	0.004
Ovary(L)	(%)	-	-	-	10	0.026	0.005	-	-	-	10	0.024	0.005
Urinary bladder	(%)	10	0.027	0.005	10	0.028	0.004	10	0.023	0.005	10	0.023	0.004

Table 6-3. Absolute and relative organ weight

\*Data collection period : 17-Sep-99 to 16-Jun-00

\*Method : B.W. and organ weight measurement were performed after 24-hour fasting period.

	Unit	52 weeks						104 weeks					
		Male			Female			Male			Female		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Body weight	(g)	10	504.70	28.72	10	250.1	31.60	10	574.80	61.87		340.7	31.12
Absolute organ weight													
Brain	(mg)	10	2148	158	10	1884	155	10	2098	166	10	1999	154
Pituitary gland	(mg)	10	10.2	0.9	10	15.4	1.7	10	24.1	37.3	10	25.0	22.2
Heart	(mg)	10	1106.0	95.7	10	654.7	52.5	10	1356.0	88.8	10	860.0	95.7
Lung	(mg)	10	1229.5	129.7	10	825.5	74.9	10	1432.2	128.5	10	970.5	42.5
Stomach	(mg)	10	2081.1	242.4	10	1335.8	133.9	10	2492.4	232.3	10	1658.9	209.1
Liver	(mg)	10	11131	927	10	5559	741	10	14708	2221	10	7130	781
Spleen	(mg)	10	771.2	114.3	10	538.8	55.0	10	1198.5	296.9	10	637.8	108.5
Kidney(R)	(mg)	10	1245.7	117.8	10	737.9	71.8	10	1841.5	304.8	10	1000.2	73.5
Kidney(L)	(mg)	10	1206.9	130.1	10	713.8	88.3	10	1718.7	237.3	10	951.2	56.6
Kidneys	(mg)	10	2452.6	242.8	10	1451.7	155.2	10	3560.2	534.1	10	1951.4	121.7
Adrenal(R)	(mg)	10	24.0	4.0	10	26.0	5.0	10	33.6	4.3	10	40.0	31.2
Adrenal(L)	(mg)	10	26.0	3.7	10	29.5	7.9	10	35.3	6.6	10	33.0	6.1
Adrenals	(mg)	10	50.0	7.6	10	55.5	12.7	10	68.9	9.8	10	72.9	33.2
Seminal vesicle	(mg)	10	1359.9	315.5	-	-	-	10	1617.5	884.2	-	-	-
Uterus	(mg)	-	-	-	10	720.1	220.5	-	-	-	10	628.4	365.8
Testis(R)	(mg)	10	1789.5	124.0	-	-	-	10	1896.7	169.0	-	-	-
Testis(L)	(mg)	10	1794.8	98.8	-	-	-	10	1854.5	229.1	-	-	-
Ovary(R)	(mg)	-	-	-	10	50.6	15.2	-	-	-	10	61.6	53.4
Ovary(L)	(mg)	-	-	-	10	49.8	16.9	-	-	-	10	55.3	15.7
Urinary bladder	(mg)	10	128.7	30.3	10	61.3	9.7	10	140.7	25.4	10	94.7	19.7
Relative organ weight													
Brain	(%)	10	0.426	0.034	10	0.763	0.106	10	0.368	0.042	10	0.591	0.069
Pituitary gland	(%)	10	0.002	0.000	10	0.006	0.001	10	0.004	0.007	10	0.008	0.008
Heart	(%)	10	0.219	0.012	10	0.263	0.018	10	0.238	0.022	10	0.255	0.038
Lung	(%)	10	0.244	0.027	10	0.332	0.022	10	0.250	0.023	10	0.287	0.028
Stomach	(%)	10	0.413	0.048	10	0.537	0.050	10	0.438	0.059	10	0.490	0.075
Liver	(%)	10	2.209	0.185	10	2.232	0.221	10	2.558	0.281	10	2.106	0.293
Spleen	(%)	10	0.153	0.021	10	0.217	0.020	10	0.209	0.050	10	0.188	0.032
Kidney(R)	(%)	10	0.247	0.024	10	0.296	0.018	10	0.321	0.051	10	0.296	0.034
Kidney(L)	(%)	10	0.240	0.025	10	0.286	0.017	10	0.300	0.039	10	0.282	0.035
Kidneys	(%)	10	0.487	0.048	10	0.582	0.030	10	0.622	0.088	10	0.577	0.068
Adrenal(R)	(%)	10	0.005	0.001	10	0.010	0.002	10	0.006	0.001	10	0.012	0.011
Adrenal(L)	(%)	10	0.005	0.001	10	0.012	0.003	10	0.006	0.001	10	0.010	0.002
Adrenals	(%)	10	0.054	0.002	10	0.022	0.005	10	0.012	0.002	10	0.022	0.011
Seminal vesicle	(%)	10	0.293	0.066	-	-	-	10	0.286	0.172	-	-	-
Uterus	(%)	-	-	-	10	0.297	0.112	-	-	-	10	0.192	0.130
Testis(R)	(%)	10	0.356	0.032	-	-	-	10	0.333	0.042	-	-	-
Testis(L)	(%)	10	0.357	0.032	-	-	-	10	0.326	0.054	-	-	-
Ovary(R)	(%)	-	-	-	10	0.020	0.006	-	-	-	10	0.018	0.014
Ovary(L)	(%)	-	-	-	10	0.020	0.005	-	-	-	10	0.016	0.004
Urinary bladder	(%)	10	0.026	0.006	10	0.025	0.003	10	0.025	0.006	10	0.028	0.007

Table 7-1. Histopathological findings

\*Data collection period : 18-Jan-00 to Oct-01

\*Method : Hematoxylin eosin staining after fixation with 10% phosphate buffered formalin solution.

\*Examination : Toshimi Usui D.V.M., Ph.D., Central Institute for Experimental Animals (CIEA)

Organ	Findings	5 weeks (n=10)		10 weeks (n=10)		18 weeks (n=10)	
		Male	Female	Male	Female	Male	Female
Heart	No abnormal changes	10	10	10	10	10	10
Lung	No abnormal changes	10	10	10	10	10	10
Liver	No abnormal changes	10	10	10	10	10	10
Kidney	Pelvic dilation	1	0	1	0	0	0
	Pelvic mineralization	0	0	0	1	0	0
	Corticomedullary mineralization	0	0	2	9	0	6
	Interstitial cell infiltration	0	0	0	0	1	0
	No abnormal changes	9	10	7	0	9	4
Spleen	No abnormal changes	10	10	10	10	10	10
Testes	Tubular atrophy	-	-	-	-	1	-
	No abnormal changes	-	-	-	-	9	-
Postate	Lymphoid cell foci	-	-	-	-	6	-
	No abnormal changes	-	-	-	-	4	-
Ovary	No abnormal changes	-	-	-	-	-	10
Uterus	No abnormal changes	-	-	-	-	-	10
Vagina	No abnormal changes	-	-	-	-	-	10
Urinary bladder	No abnormal changes	-	-	-	-	10	10

Table 7-2. Histopathological findings

\*Data collection period : 18-Jan-00 to Oct-01

\*Method : Hematoxylin eosin staining after fixation with 10% phosphate buffered formalin solution.

\*Investigation : Toshimi Usui D.V.M., Ph.D., Central Institute for Experimental Animals

Organ Findings	104 weeks (n=10)	
	Male	Female
<b>Heart</b>		
Minute myocardial necrosis (left ventricle)	1	-
Small focus of cellular infiltration (subepicardial)	1	-
Interstitial fibrosis (minimal)	1	-
Myocardial necrosis/monocytic infiltration (slight)	1	-
No abnormal changes	7	10
<b>Lung</b>		
Subpleural macrophage aggregate, cholesterol crystal	-	1
No abnormal changes	10	9
<b>Liver</b>		
Focal hepatocellular fatty vacuolation	1	-
Focal perivascular monocytic infiltration	1	-
Occasional foci of hepatocellular fatty vacuolation	-	-
Bile duct proliferation (slight)	-	2
No abnormal changes	9	8
<b>Kidney</b>		
Pelvic dilation	-	-
Pelvic mineralization	-	-
Corticomedullary mineralization	-	-
Interstitial cell infiltration	-	-
Chronic nephropathy (moderate)	2	-
Chronic nephropathy (slight)	3	-
Chronic nephropathy (minimal)	5	-
No abnormal changes	-	10
<b>Spleen</b>		
No abnormal changes	10	10
<b>Testes</b>		
Tubular atrophy	-	-
No abnormal changes	-	-
<b>Prostate</b>		
Lymphoid cell foci	-	-
No abnormal changes	-	-
<b>Ovary</b>		
No abnormal changes	-	-
<b>Uterus</b>		
No abnormal changes	-	-
<b>Vagina</b>		
No abnormal changes	-	-
<b>Urinary bladder</b>		
No abnormal changes	-	-
<b>Subcutaneous mass</b>		
Malignant trichoepithelioma	1	-
<b>Adrenal</b>		
Cortical adenoma	-	1

Table 8. Comparison of gene frequencies

\*Examination .Central Institute for Experimental Animals (CIEA), ICLAS monitoring center

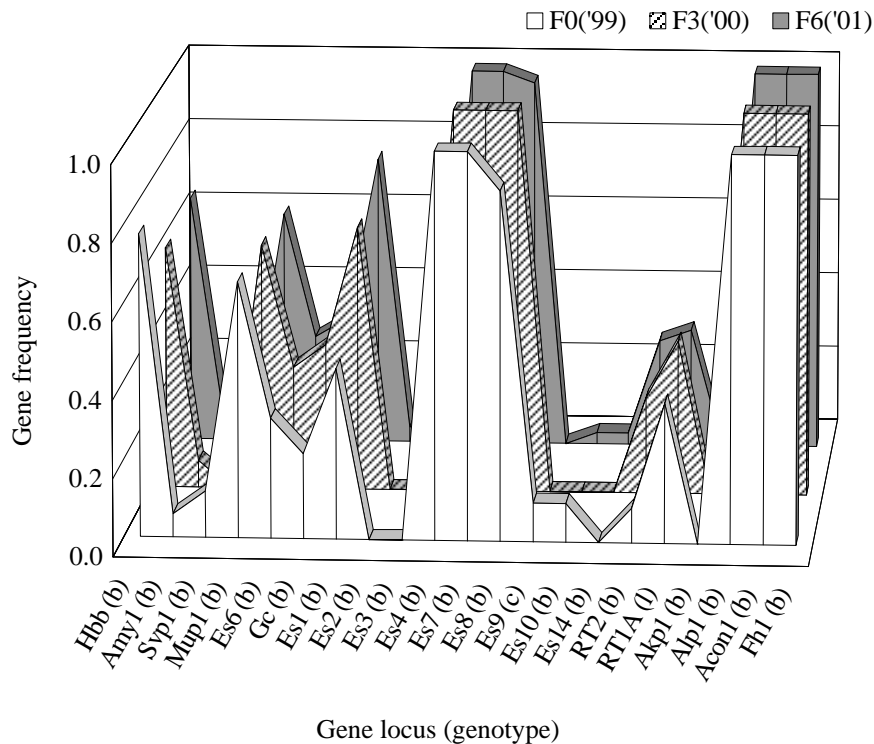
Gene locus	No. of Chr.	F0		F2			F6			
		Date :99. 3. 3	n :Female6, Male=26	Date :00. 2.18	n Female=36, Male=36	Date :01. 3.27	n Female=36, Male=36			
<i>Hbb</i>	1	a: 0.22	b: 0.78	a: 0.38	b: 0.63	a: 0.35	b: 0.65			
<i>Amy1</i>	2	a: 0.94	b: 0.06	a: 0.93	b: 0.07	a: 0.92	b: 0.08			
<i>Syp1</i> <sup>‡1</sup>	3	a: 0.88	b: 0.12	a: ND <sup>¶</sup>	b: ND <sup>¶</sup>	a: 0.89	b: 0.11			
<i>Mup1</i>	5	a: 0.34	b: 0.66	a: 0.36	b: 0.64	a: 0.39	b: 0.61			
<i>Es6</i> <sup>‡1</sup>	8	a: 0.69	b: 0.31	a: 0.68	b: 0.32	a: 0.72	b: 0.28			
<i>Gc</i>	14	a: 0.78	b: 0.22	a: 0.62	b: 0.38	a: 0.67	b: 0.33			
<i>Es1</i>	19	a: 0.56	b: 0.44	a: 0.31	b: 0.69	a: 0.24	b: 0.76			
<i>Es2</i>	19	a: 0.89	d: 0.11	a: 0.96	d: 0.04	a: 0.96	d: 0.04			
<i>Es3</i>	19	a: 0.92	d: 0.08	a: 0.97	d: 0.03	a: 0.97	d: 0.03			
<i>Es4</i>	19	a: 0.00	b: 1.00	a: 0.00	b: 1.00	a: 0.00	b: 1.00			
<i>Es7</i> <sup>‡1</sup>	19	a: 0.00	b: 1.00	a: 0.00	b: 1.00	a: 0.00	b: 1.00			
<i>Es8</i> <sup>‡1</sup>	19	a: 0.10	b: 0.90	a: 0.00	b: 1.00	a: 0.03	b: 0.97			
<i>Es9</i> <sup>‡1</sup>	19	a: 0.90	b: 0.00	c: 0.10	a: 1.00	b: 0.00	c: 0.00	a: 0.97	b: 0.03	c: 0.00
<i>Es10</i> <sup>‡1</sup>	19	a: 0.90	b: 0.10	a: 1.00	b: 0.00	a: 0.97	b: 0.03			
<i>Es14</i> <sup>‡2</sup>	19	a: 1.00	b: 0.00	a: 1.00	b: 0.00	a: 0.97	b: 0.03			
<i>RT2</i>	19	a: 0.91	b: 0.09	a: 0.75	b: 0.25	a: 0.72	b: 0.28			
<i>RT1A</i>	20	a: 0.16	l: 0.36	u: 0.48	a: 0.22	l: 0.40	u: 0.38	a: 0.27	l: 0.31	u: 0.42
<i>Akp1</i>	-	a: 1.00	b: 0.00	a: 1.00	b: 0.00	a: 1.00	b: 0.00			
<i>Alp1</i>	-	a: 0.00	b: 1.00	a: 0.00	b: 1.00	a: 0.00	b: 1.00			
<i>Acon1</i>	5	a: 0.00	b: 1.00	a: 0.00	b: 1.00	a: 0.00	b: 1.00			
<i>Fhl</i>	13	a: 0.00	b: 1.00	a: 0.00	b: 1.00	a: 0.00	b: 1.00			

<sup>‡1</sup> Males only

<sup>‡2</sup> Femals only

<sup>¶</sup> No samples

Distribution patterns of gene frequencies





## TWO-YEAR STUDY DATA

**Baseline Reproductive Data**  
for Wistar Hannover GALAS rats, collected by RCC, Switzerland

**Includes:**

**Body Weight and Malformation Rats**

**Reproduction Data**

**Spontaneous Abnormal Findings**

**Skeletal examination of fetuses**

### Female Body Weight and Pup Malformation Rates

#### Female Body Weights

Number of dams	130
Number of fetuses	1634
Mean body weight on day 0 P.C.* (g)	220
Mean body weight on day 20 P.C. (g)	331
Mean body weight gain days 0-20 P.C. (g)	111
Mean body weight gain days 0-20 P.C. (%)	50.6
Mean food consumption days 0-20 P.C. (g/day)	23.3

#### Malformation/Anomalies

##### External examination

N (fetuses basis)	2
% per fetus	0.1
N (litter basis)	2
% per litter	1.5

##### Visceral examination

N (fetuses basis)	1
% per fetus	0.1
N (litter basis)	1
% per litter	0.8

##### Skeletal examination

N (fetuses basis)	24
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% per fetus	2.8
N (litter basis)	19
% per litter	14.6

\*P.C.= Post coitum

## Reproductive Data

Number of females mated	135
Pregnant	130
Used for calculation	130
Corpora lutes	1815
Mean	14.0
Pre-implantation loss	102
% of corp. lutea	5.6
Mean	0.8
Number of dams affected	58
Implantation site	1713
% of corp. lutea	94.4
Mean	13.2
Post-implantation loss	79
% of corp. lutea	4.6
Mean	0.6
Number of dams affected	52
Implantation site scars	0
Embryonic deaths : total	79
Embryonic resorptions	70
% of impl. Site	4.1
Mean	0.6
Number of dams affected	49
Fetal resorptions	9
% of impl. Site	0.5
Mean	0.1
Number of dams affected	16
<b>Fetuses</b>	
Total fetuses	1634
% of impl. Site	95.4
Mean	12.6
Live fetuses	1634
Dead fetuses	0



Malformed fetuses	2
% of fetuses	0.1
Mean	0.02
Number of dams affected	2

Malformed live fetuses at external examination 2

Malformed dead fetuses at external examination 0

### Sex of fetuses

Total males	804
% of fetuses	49.2
Mean	6.2

Total females	830
% of fetuses	50.8
Mean	6.4

### Weight of live fetuses

*(Litter basis)*

Males and females

N (litters)	130
Mean	4.7

Males

N (litters)	130
Mean	4.8

Females

N (litters)	130
Mean	4.6

*(Individual basis)*

Males and females

N (fetuses)	1360
Mean	4.7

Males

N (fetuses)	664
Mean	4.8

Females

N (fetuses)	696
Mean	4.6

### Spontaneous abnormal findings

Number of litters/fetuses	130	1634
Number of fetuses for visceral/skeletal examination	787	847

**Abnormal findings**

**Number affected**

	<b>Fetuses</b>	<b>Litters</b>
	#	#
	%	%
Abnormally shaped sternebra Nos. 3 and 4	4	4
	0.5	3.1
Abnormally shaped sternebra Nos. 4 and 5	5	5
	0.6	3.9
Abnormally shaped sternebra Nos. 3-5	1	1
	0.1	0.8
Agnathia (lower jaw)	1	1
	0.1	0.8
Cleft palate	1	1
	0.1	0.8
Wavy ribs Nos. 8-12 (right side)	2	2
	0.2	1.6
Wavy ribs Nos. 9-12 (right side)	4	4
	0.5	3.1
Wavy ribs Nos. 10-12 (right side)	2	2
	0.2	1.6
Cleft palate, forelimbs deformed	1	1
	0.1	0.8
Upper and lower jaw shortened deformed and distal fused; forelimbs; radius, ulna, humerus and scapula bilateral deformed and shortened; Abnormally shaped sternebra Nos. 3-5; wavy and shortened ribs Nos. 1-13 (left and right side)	1	1
	0.1	0.8
Dumbbell shaped thoracic vertebral body No. 10	1	1
	0.1	0.8
Wavy ribs Nos. 9-12 (right side) and Nos. 9-13 (left side)	1	1
	0.1	0.8
Wavy ribs Nos. 11-12 (right side) and Nos. 10-12 (left side)	1	1
	0.1	0.8
Wavy ribs Nos. 8-12 (right side) and Nos. 10-12 (left side)	1	1
	0.1	0.8

Wavy ribs Nos. 10-12 (right side) and Nos. 11-12 (left side), dumbbell shaped thoracic vertebral body No. 12

1 1  
0.1 0.8

### Skeletal examination of fetuses (stage of development)

Number of litters/fetuses for skeletal examination	847		130	
Findings	Fetuses affected		Litters affected	
	#	(%)	#	(%)
<u>CRANIUM</u>				
INCOMPLETELY OSSIFIED				
-os occipitale	24	2.8	16	12.3
-os parietale, bilateral	32	3.7	16	12.4
-os interparietale	123	14.5	57	44.0
<u>CERVICAL VERTEBRAE</u>				
NON-OSSIFIED				
-cervical vertebra 1	107	12.4	57	43.8
-cervical vertebra 2	57	6.8	36	27.8
-cervical vertebra 3	14	1.6	10	7.6
-cervical vertebra 4	4	0.5	2	1.6
-cervical vertebra 5	2	0.2	2	1.6
-cervical vertebra 6	0	0.0	0	0.0
-cervical vertebra 7	0	0.0	0	0.0
DUMBBELL SHAPE				
-cervical vertebrae 1	176	20.7	82	63.4
BIPARTITE				
-cervical vertebrae 1	11	1.3	8	6.4
<u>STERNUM</u>				
INCOMPLETELY OSSIFIED				
-sternebra 1	2	0.2	2	1.5
-sternebra 2	113	13.4	72	49.0
-sternebra 3	0	0.0	0	0.0
-sternebra 4	28	3.3	22	17.0
-sternebra 5	516	60.8	127	97.2
-sternebra 6	11	1.4	11	8.4
NON-OSSIFIED				
-sternebra 1	0	0.0	0	0.0
-sternebra 2	0	0.0	0	0.0
-sternebra 3	0	0.0	0	0.0
-sternebra 4	0	0.0	0	0.0
-sternebra 5	3	0.4	3	2.3
-sternebra 6	0	0.0	1	0.8
ABNORMALLY OSSIFIED				
-sternebra 3	0	0.0	0	0.0
-sternebra 4	8	1.1	8	6.2

-sternebra 5	12	1.4	11	8.5
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RIB(S) LEFT

SUPERNUMERARY RIB(S),

-one	39	4.9	29	22.3
------	----	-----	----	------

RUDIMENTARY SUPERNUMERARY RIB(S),

-one	14	1.7	13	10.2
------	----	-----	----	------

RIB(S) RIGHT

SUPERNUMERARY RIB(S),

-one	35	4.1	28	21.5
------	----	-----	----	------

RUDIMENTARY SUPERNUMERARY RIB(S),

-one	9	1.1	8	6.3
------	---	-----	---	-----

LEFT FORELIMB

NON-OSSIFIED

-digit 1 distal phalanx	48	5.7	27	20.9
-------------------------	----	-----	----	------

-metacarpalia 2	0	0.0	0	0.0
-----------------	---	-----	---	-----

-digit 2 proximal phalanx	264	31.1	95	73.2
---------------------------	-----	------	----	------

-digit 2 distal phalanx	89	10.8	51	39.4
-------------------------	----	------	----	------

-metacarpalia 3	0	0.1	1	0.8
-----------------	---	-----	---	-----

-digit 3 proximal phalanx	27	3.1	18	13.8
---------------------------	----	-----	----	------

-digit 3 distal phalanx	3	0.4	4	3.0
-------------------------	---	-----	---	-----

-metacarpalia 4	0	0.0	1	0.8
-----------------	---	-----	---	-----

-digit 4 proximal phalanx	45	5.3	30	23.1
---------------------------	----	-----	----	------

-digit 4 distal phalanx	20	2.4	16	12.4
-------------------------	----	-----	----	------

-metacarpalia 5	2	0.2	2	1.5
-----------------	---	-----	---	-----

-digit 5 proximal phalanx	465	55.2	117	90.1
---------------------------	-----	------	-----	------

-digit 5 distal phalanx	385	45.4	110	84.8
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RIGHT FORELIMB

NON-OSSIFIED

-digit 1 distal phalanx	47	5.6	27	20.9
-------------------------	----	-----	----	------

-metacarpalia 2	0	0.0	0	0.0
-----------------	---	-----	---	-----

-digit 2 proximal phalanx	258	30.4	97	74.7
---------------------------	-----	------	----	------

-digit 2 distal phalanx	87	9.1	50	38.6
-------------------------	----	-----	----	------

-metacarpalia 3	0	0.0	0	0.0
-----------------	---	-----	---	-----

-digit 3 proximal phalanx	20	4.9	15	11.5
---------------------------	----	-----	----	------

-digit 3 distal phalanx	3	0.4	3	2.3
-------------------------	---	-----	---	-----

-metacarpalia 4	0	0.0	0	0.0
-----------------	---	-----	---	-----

-digit 4 proximal phalanx	39	4.0	26	20.0
---------------------------	----	-----	----	------

-digit 4 distal phalanx	17	2.0	13	10.0
-------------------------	----	-----	----	------

-metacarpalia 5	1	0.1	1	0.8
-----------------	---	-----	---	-----

-digit 5 proximal phalanx	447	52.7	119	91.6
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-digit 5 distal phalanx	381	45.0	107	82.5
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## LEFT HIND LIMB

### NON-OSSIFIED

-talus	465	55.1	113	87.1
-metatarsalia 1	80	9.5	45	34.6
-toe 1 distal phalanx	3	0.4	3	2.3
-metatarsalia 2	0	0.0	0	15.9
-toe 2 proximal phalanx	537	62.3	122	78.0
-toe 2 medial phalanx	0	0.0	1	0.8
-toe 2 distal phalanx	2	0.2	1	0.8
-metatarsalia 3	0	0.0	0	0.0
-toe 3 proximal phalanx	281	33.2	94	63.6
-toe 3 medial phalanx	1	0.1	0	0.0
-toe 1 distal phalanx	1	0.1	2	1.5
-metatarsalia 4	0	0.0	0	0.0
-toe 4 proximal phalanx	264	31.2	89	59.7
-toe 4 medial phalanx	1	0.1	1	0.8
-toe 4 distal phalanx	1	0.1	1	0.8
-metatarsalia 5	0	0.0	0	0.0
-toe 5 proximal phalanx	723	85.4	129	99.2
-toe 5 medial phalanx	0	0.0	0	0.0
-toe 5 distal phalanx	4	0.5	4	3.1

## RIGHT HIND LIMB

### NON-OSSIFIED

-talus	482	57.1	112	86.3
-metatarsalia 1	82	10.1	46	35.3
-toe 1 distal phalanx	3	0.4	3	3.8
-metatarsalia 2	0	0.0	0	0.0
-toe 2 proximal phalanx	570	67.2	124	95.4
-toe 2 medial phalanx	0	0.0	0	0.0
-toe 2 distal phalanx	2	0.2	2	1.5
-metatarsalia 3	0	0.0	0	0.0
-toe 3 proximal phalanx	314	37.1	99	76.2
-toe 3 medial phalanx	0	0.0	0	0.0
-toe 3 distal phalanx	2	0.2	2	1.5
-metatarsalia 4	0	0.0	0	0.0
-toe 4 proximal phalanx	285	33.7	95	73.0
-toe 4 medial phalanx	0	0.0	0	0.0
-toe 4 distal phalanx	2	0.2	2	1.5
-metatarsalia 5	0	0.0	0	0.0
-toe 5 proximal phalanx	717	84.7	130	100.0
-toe 5 medial phalanx	0	0.0	0	0.0
-toe 5 distal phalanx	4	0.5	4	3.1

Wistar Hannover Rat – Most Common Neoplastic Findings by Organ or Tissue in Male and Female Control Animal Sacrificed after 103 Weeks, collected by RCC, Switzerland.

<u>ORGAN/finding</u>	<u>Male N</u>	<u>% of total</u>	<u>Female N</u>	<u>% of Total</u>
<b>BRAIN</b>	<b>2280</b>		<b>2256</b>	
Granular cell tumor		2.28		1.06
Astrocytoma		0.48		0.22
Oligodendroglioma		0.13		0.13
Mixed glioma		0.13		0.18
<b>SPINAL CORD</b>	<b>1429</b>		<b>1425</b>	
Neurinoma (b and m)		0.14		0
Tumor (NOS)		0.07		0
<b>HARDERIAN GLS.</b>	<b>1705</b>		<b>1539</b>	
Cystadenoma		0.23		0
Squamous cell carcinoma		0.12		0
<b>ZYMBAL GLANDS</b>	<b>108</b>		<b>116</b>	
Carcinoma		0.93		0
Adenoma		0		0.86
<b>EYES</b>	<b>1815</b>		<b>1838</b>	
Neurinoma (b and m)		0		0.11
<b>EARS</b>	<b>1</b>		<b>10</b>	
Sebaceous papilloma		0		10
Sebaceous carcinoma		100		40
Neural crest tumor		0		20
<b>HEART</b>	<b>1872</b>		<b>1861</b>	
Endocardial sarcoma		1.39		1.02
Paranglioma		0.05		0
Hemangiosarcoma		0.05		0
<b>LUNGS</b>	<b>2222</b>		<b>2095</b>	
Adenoma		0.41		0.14
Carcinoma		0.23		0.05
Squamous cell carcinoma		0.05		0.05
<b>PITUITARY</b>	<b>2312</b>		<b>2323</b>	
Adenoma, pars distalis		41.05		65.78
Adenoma, pars intermedia		0.04		0.04
Adenocarcinoma		0		0.09
Pituicytoma		0		0.09
<b>ADRENALS</b>	<b>1559</b>		<b>1554</b>	
Pheochromocytoma (b)		3.91		1.42
Cortical adenoma		2.57		2.51
Pheochromocytoma (m)		1.41		0.32
<b>ADRENAL CORTEX</b>	<b>1120</b>		<b>1118</b>	
Adenoma		1.34		1.79
Carcinoma		0.18		0.09
Hemangioma		0		0.09
<b>ADRENAL MEDULLA</b>	<b>1326</b>		<b>1278</b>	
Pheochromocytoma (b)		3.17		1.25
Pheochromocytoma (m)		0.83		0.31
<b>THYROID GLANDS</b>	<b>2425</b>		<b>2428</b>	
C-cell adenoma		10.06		10.67
Follicular adenoma		3.09		1.85
C-cell carcinoma		1.4		1.32
Follicular carcinoma		0.82		0.29
<b>PARATHYROID GLS.</b>	<b>2045</b>		<b>1870</b>	
Adenoma		1.56		0.48

<b>PANCREAS, EXO.</b>	<b>2107</b>		<b>2047</b>	
Adenoma		1.42		0.05
Carcinoma		0.43		0
Mixed-cell adenoma		0.05		0
<b>PANCREAS, ENDO.</b>	<b>2215</b>		<b>2183</b>	
Islet cell adenoma		5.33		1.88
Islet cell carcinoma		1.94		0.6
<b>LIVER</b>	<b>2340</b>		<b>2310</b>	
Adenoma		2.01		3.2
Carcinoma		0.3		0.56
Hepatocellular nodule		0.21		0.35
Hemangioma		0.17		0
<b>STOMACH</b>	<b>2164</b>		<b>1934</b>	
Squamous cell carcinoma		0.18		0.1
Papilloma		0.14		0
Fibrosarcoma		0.05		0.05
Leiomyosarcoma		0		0.05
<b>SMALL INTESTINE</b>	<b>1375</b>		<b>1403</b>	
Neurinoma (m)		0.07		0
<b>DUODENUM</b>	<b>547</b>		<b>704</b>	
Leiomyoma		0.18		0.28
Adenocarcinoma		0.18		0
Histiocytic sarcoma		0		0.14
<b>JEJUNUM</b>	<b>571</b>		<b>568</b>	
Adenomatous polyp		0.18		0
Leiomyoma		0.18		0.18
Adenocarcinoma		0.18		0
Leiomyosarcoma		0.18		0
<b>ILEUM</b>	<b>271</b>		<b>225</b>	
Neurinoma		0.37		0
<b>LARGE INTESTINE</b>	<b>1382</b>		<b>1413</b>	
Leiomyoma		0.14		0.07
Lipoma		0.14		0
Fibroma		0.07		0.07
Mesothelioma		0.07		0
Fibrosarcoma		0		0.07
<b>RECTUM</b>	<b>435</b>		<b>387</b>	
Hemangioma		0		0.26
<b>SUBMANDIBULAR GL</b>	<b>1685</b>		<b>1611</b>	
Adenocarcinoma		0.12		0.12
Neurinoma (m)		0.12		0
Adenoma		0.06		0.06
<b>PAROTID GLANDS</b>	<b>2</b>		<b>3</b>	
Schwannoma (m)		50		0
Adenocarcinoma		0		100
<b>SALIVARY GL(NOS)</b>	<b>47</b>		<b>50</b>	
Myoepithelioma		6.38		0
Sarcoma (NOS)		4.26		0
<b>KIDNEYS</b>	<b>2440</b>		<b>2164</b>	
Tubular adenoma		0.33		0.18
Lipoma		0.25		0.23
Liposarcoma		0.25		0.09
Transitional carcinoma		0.2		0

<b>URINARY BLADDER</b>	<b>1709</b>		<b>1754</b>	
Polyp		0.12		0
Transitional cell papilloma		0.06		0.06
<b>SKIN</b>	<b>2233</b>		<b>2191</b>	
Fibroma		4.16		1.1
Keratoacanthoma		3.63		0
Papilloma		1.25		0.18
Lipoma		0.99		0.59
Squamous cell carcinoma		0.9		0.32
Neurinoma (m)		0.76		0.18
<b>TESTES</b>	<b>2439</b>			
Leydig cell tumor (b)		4.31		
Mesothelioma		0.16		
Hemangioma		0.08		
<b>EPIDIDYMIDES</b>	<b>1788</b>			
Adenocarcinoma		0.06		
Mesothelioma		0.06		
<b>PROSTATE GLAND</b>	<b>1896</b>			
Adenoma		0.21		
Adenocarcinoma		0.11		
<b>SEMINAL VESICLES</b>	<b>1951</b>			
Adenocarcinoma		0.1		
Adenoma		0.05		
<b>MAMMARY GLANDS</b>	<b>1128</b>		<b>2322</b>	
Fibroadenoma		1.24		30.23
Adenocarcinoma		0.44		4.65
Adenoma		0.18		1.55
Carcinoma, NOS		0.09		0.43
Carcinosarcoma		0		0.3
<b>OVARIES</b>			<b>2437</b>	
Theca-granulosa cell tumor (b)				1.76
Granulosa cell tumor (b)				0.62
Sertoli cell tumor				0.33
Theca-granulosa cell tumor (m)				0.33
Theca cell tumor (b)				0.12
<b>UTERUS</b>			<b>2224</b>	
Polyp, stromal				4.27
Adenocarcinoma				3.37
Polyp, endometrial				2.74
Stromal sarcoma				0.58
Adenoma				0.49
<b>VAGINA</b>			<b>564</b>	
Polyp stromal				0.89
Squamous cell carcinoma				0.18
Fibroma				0.18
Leiomyoma				0.18
Neurofibroma (b)				0.18
<b>HEMOLYMPHORETICULAR</b>	<b>2162</b>		<b>2182</b>	
Lymphoma		3.75		4.03
Histiocytoma		1.16		0.69
Fibrous histiocytoma		0.28		0.14
Myeloid leukemia		0		0.23



<b>BONE MARROW</b>	<b>1350</b>		<b>1347</b>	
Hemangioma		0.07		0
Plasma cell myeloma		0.07		0
<b>SPLEEN</b>	<b>2299</b>		<b>2096</b>	
Hemangiosarcoma		0.39		0.19
Hemangioma		0.26		0.29
Sarcoma, NOS		0.04		0
Histiocytoma		0		0.05
<b>MESENTERIC L.N.</b>	<b>2311</b>		<b>2281</b>	
Hemangioma		8.74		2.85
Hemangiosarcoma		1.25		0.53
Lymphangioma		0.04		0.04
<b>MANDIBULAR L.N.</b>	<b>1874</b>		<b>1740</b>	
Hemangioma		0.05		0.06
<b>OTHER L.N.</b>	<b>222</b>		<b>208</b>	
Hemangiosarcoma		1.35		0.48
Hemangioma		0.45		1.92
<b>THYMUS</b>	<b>1853</b>		<b>2018</b>	
Thymoma (m)		0.92		0.35
Thymoma (b)		0.16		0.69
Adenocarcinoma		0		0.1
<b>ORAL CAV/SOFT PAL.</b>	<b>46</b>		<b>49</b>	
Squamous cell carcinoma		4.35		0
Papilloma		2.17		0
<b>NASAL CAVITY</b>	<b>203</b>		<b>256</b>	
Neurinoma (m)		0.49		0
Carcinoma, NOS		0		0.39
<b>BONES-OTHER</b>	<b>1287</b>		<b>1242</b>	
Osteosarcoma		0.23		0
Osteoma		0.16		0.16
<b>BONE-STERNUM</b>	<b>220</b>		<b>220</b>	
Carcinoasarcoma			0.45	0
<b>BONE-FEMUR</b>	<b>200</b>		<b>90</b>	
Osteofibroma		0.5		0
Osteosarcoma		0.5		0
<b>SKELETAL MUSCLE</b>	<b>1586</b>		<b>1534</b>	
Hemangiosarcoma		0.13		0
Neurinoma (m)		0.06		0
<b>TONGUE</b>	<b>1036</b>		<b>964</b>	
Granular cell tumor		0.19		0
Papilloma		0.1		0.41
<b>BODY CAVITIES</b>	<b>225</b>		<b>229</b>	
Lipoma		8.44		11.35
Mesothelioma		2.67		1.75
Hemangiosarcoma		0.89		0
Fibroma		0.44		2.18
<b>ADIPOSE TISSUE</b>	<b>5</b>		<b>5</b>	
Lipoma		20		60
Hibernoma		20		0
<b>JOINT</b>	<b>400</b>		<b>350</b>	
Fibrosarcoma		0.25		0

Wistar Hannover Rat – Most Commonly Observed Non-neoplastic Findings by Organ or Tissue in Male and Female Control Animals Sacrificed after 103 Weeks collected by RCC, Switzerland.

<u>ORGAN/finding</u>	<u>Male N</u>	<u>% of Total</u>	<u>Female N</u>	<u>% of Total</u>
<b>BRAIN</b>	<b>2138</b>		<b>2130</b>	
Compression		17.91		31.55
Ventricular dilation		8.33		13.42
Radiculoneuropathy		1.59		2.07
Mineralization		1.12		0.09
Gliosis		0.65		1.27
Hemorrhage		0.56		0.89
Necrosis		0.47		0.8
<b>SPINAL CORD</b>	<b>2051</b>		<b>2002</b>	
Radiculoneuropathy		17.23		14.64
Vacuolation		2.15		2.15
Gliosis		0.85		0.6
Inflammation		0.73		0.7
Necrosis		0.68		0.8
Dural Ossification		0.68		0.45
<b>SCIATIC NERVE</b>	<b>1918</b>		<b>1898</b>	
Degeneration		44.06		42.31
Lymphoid Cell Foci		0.21		0.11
Mineralization		0.16		0.05
<b>OPTIC NERVES</b>	<b>1083</b>		<b>1026</b>	
Mineralization		1.29		0.58
Degeneration		1.11		2.44
Inflammatory Foci		0.18		0.19
Inflammation		0.09		0.10
<b>EYES</b>	<b>2218</b>		<b>2244</b>	
Hemorrhage		6.13		5.97
Retinal Degeneration		5.09		6.68
Lenticular Degeneration		3.97		3.79
Keratitis		3.16		1.78
Iritis		2.39		1.16
Panophthalmitis		1.98		1.52
Retrob. Inflammation		0.72		1.07
<b>HARDERIAN GLAND</b>	<b>2087</b>		<b>2093</b>	
Inflammation		29.61		28.48
Pigment Deposition		19.12		16.77
Lymphoid Cell Foci		12.7		13.14
Dilated Cystic Glands		3.69		3.63
Hyperplasia		1.77		0.57
Granulomas		1.58		1.82
Atrophy		1.39		1.39
<b>LACRIMAL GLANDS</b>	<b>209</b>		<b>59</b>	
Inflammation		68.9		1.69
Chromodacryorrhoe		31.58		1.69
Vacuolation		20.57		5.08
Glandular ectasia		20.1		5.08
Ductal ectasia		12.92		1.69
Acinar atrophy		12.44		3.39
Lymphoid cell foci		10.05		6.78
<b>EX. LACRIMAL GL.</b>	<b>977</b>		<b>510</b>	
Inflammation		46.16		15.1

Harderian alteration		42.89		16.08
Page 2				
Lymphoid cell foci		28.05		8.63
Atrophy		12.9		1.57
Cytoplasmic vacuolation		9.42		2.35
Glandular ectasia		9.42		1.57
<b>Zymbal's glands</b>	<b>68</b>		<b>70</b>	
Cystic change		36.76		42.86
Inflammation		4.41		2.86
<b>AORTA</b>	<b>1916</b>		<b>1679</b>	
Mineralization		4.07		0.36
Inflammation		0.47		0.06
<b>HEART</b>	<b>2211</b>		<b>2180</b>	
Myofibrosis/necrosis		52.83		30.87
Lymphoid cell foci		16.1		8.53
Cardiomyopathy		15.15		8.3
Myocarditis		6.29		4.59
Myocardial mineralization		3.26		0.41
Congestion		1.31		0.41
<b>TRACHEA</b>	<b>1619</b>		<b>1554</b>	
Distended glands		8.4		8.5
Lymphoid cell foci		4.88		4.99
Inflammation		2.1		3.45
Pigment deposition		0.99		1.98
Inflammatory cell infiltrate		0.93		1.09
<b>LUNGS</b>	<b>2223</b>		<b>2176</b>	
Alveolar histiocytosis		25.55		26.84
Arterial mineralization		13.32		9.38
Congestion		12.24		6.16
Lymphoid hyperplasia		6.84		7.03
Perivascular cuffing		5.98		5.61
Mineralization		5.62		3.95
Inflammation		4.86		6.76
Fibrosis		4.72		4.83
<b>PITUITARY</b>	<b>2289</b>		<b>2292</b>	
Cyst(s)/clefts		16.38		7.9
Hyperplasia		10.97		10.82
Cystic degeneration		2.05		1.18
Altered cell focus		1.57		1.48
Angiectasis		1.44		4.28
Pigment deposition		1.05		1.0
Hemorrhage		0.35		1.09
<b>ADRENALS</b>	<b>618</b>		<b>619</b>	
Altered cell foci		49.35		35.86
Pigment deposition		41.26		42.0
Cortical vacuolation		20.39		8.4
Cortical hypertrophy		13.27		8.89
Cortical hyperplasia		10.36		7.59
Cortical hemorrh. deg.		6.63		19.71
Congestion		4.37		5.98
Cystic cortical deg.		3.72		25.2
Angiectasis		0.81		15.51
<b>ADRENAL CORTEX</b>	<b>1753</b>		<b>1740</b>	
Cellular alteration		38.9		26.44
Fatty infiltration		17.74		7.41

Accessory cortical tissue	15.4		12.53
Page 3			
Pigment deposition	15.35		20.57
Clear cell foci	14.66		13.85
Cortical hyperplasia	12.21		9.6
Angiectasis	6.27		26.72
Hypertrophic foci	5.36		6.72
Cystic degeneration	3.88		43.51
<b>ADRENAL MEDULLA</b>	<b>1827</b>	<b>1810</b>	
Medullary hyperplasia	7.99		3.59
Lymphoid cell foci	3.78		3.15
Pigment deposition	2.35		5.08
Angiectasis	1.48		2.15
Inflammation	0.33		0.55
<b>THYROID GLANDS</b>	<b>2290</b>	<b>2290</b>	
C-cell hyperplasia	30.61		31.14
Follicular cyst(s)	7.47		3.89
Follicular hyperplasia	5.15		2.71
Ultimobranchial cyst(s)	4.93		2.62
Mineralization	1.97		0.31
Lymphoid cell foci	0.87		0.92
<b>PARATHYROID GL.</b>	<b>1972</b>	<b>1885</b>	
Hyperplasia	12.68		3.87
Fibrosis	0.96		2.86
Anomaly	0.05		0.11
Cyst(s)	0.05		0.11
<b>PANCREAS</b>	<b>2276</b>	<b>2282</b>	
Pigment deposition	18.89		3.24
Islet hyperplasia	14.15		9.03
Acinar atrophy	9.05		5.83
Inflammation	5.62		5.26
Lymphoid cell foci	3.73		4.43
<b>LIVER</b>	<b>2312</b>	<b>2299</b>	
Fatty change	36.07		15.48
Clear cell foci	34.47		11.48
Basophilic foci	33.48		52.72
Bile duct hyperplasia	27.25		35.1
Inflammation	27.12		21.4
Inflammatory cell foci	26.43		25.88
Peribiliary fibrosis	18.99		20.92
Eosinophilic foci	13.75		10.92
Erythropoiesis	9.04		11.7
<b>COMMON BILE D.</b>	<b>17</b>	<b>17</b>	
Dilated lumen	88.24		82.35
Inflammation	11.76		5.88
<b>ESOPHAGUS</b>	<b>1330</b>	<b>1321</b>	
Hyperkeratosis	1.73		0.76
Inflammation	0.3		0
Dilated lumen	0.15		0.15
<b>STOMACH</b>	<b>2276</b>	<b>2280</b>	
Dilated glands	26.01		30.88
Erosion/ulceration	7.82		4.04
Inflammation	7.07		4.87
Mineralization	5.05		0.39
Hyperplasia	4.35		2.68

<b>SMALL INTESTINE</b>	<b>699</b>		<b>714</b>	
Mineralization		0.86		0
Glandular ectasia		0.57		0.28
Inflammation		0.43		0.14
Diverticulum		0.29		0
Digested blood		0.14		0.42
<b>DUODENUM</b>	<b>1336</b>		<b>1306</b>	
Inflammation		1.12		2.22
Mucosal atrophy		0.3		0.08
Mucosal hyperplasia		0		0.23
Ulceration		0		0.15
<b>JEJUNUM</b>	<b>1158</b>		<b>1214</b>	
Inflammation		1.81		2.06
Congestion		0.95		0.58
Periarteritis/arteritis		0.43		0
Diverticulum		0.26		0
Lymphoid hyperplasia		0.09		0.25
<b>ILEUM</b>	<b>1085</b>		<b>1044</b>	
Inflammation		0.92		0
Mucosal atrophy		0.37		0.1
Lymphoid hyperplasia		0.37		0.38
Congestion		0.09		0.48
<b>LARGE INTESTINE</b>	<b>711</b>		<b>728</b>	
Nematodes		9.14		7.01
Mineralization		0.84		0
Inflammation		0.7		0.14
Dilated lumen		0.7		0.55
Lymphoid hyperplasia		0.28		0.41
<b>CECUM</b>	<b>1368</b>		<b>1307</b>	
Inflammation		2.19		0.77
Ulcer(s)		0.73		0
Nematodes		0.73		0.08
Edema		0.73		0.38
Congestion		0.29		0.46
Lymphoid hyperplasia		0.07		0.69
<b>COLON</b>	<b>1500</b>		<b>1502</b>	
Nematodes		3.2		2.26
Inflammation		2.27		1.0
Lymphoid hyperplasia		1.0		0.2
Mineralization		0.8		0
<b>RECTUM</b>	<b>1092</b>		<b>1065</b>	
Nematodes		4.21		3.47
Inflammation		1.01		0.94
Mineralization		0.27		0
<b>SALIVARY GLANDS</b>	<b>805</b>		<b>807</b>	
Inflammation		2.86		3.35
Lymphoid cell foci		2.48		2.35
Alveolar atrophy		0.75		0
Ductal ectasia		0.5		1.24
<b>SUBLINGUAL GL.</b>	<b>1150</b>		<b>1214</b>	
Lymphoid cell foci		2.35		1.73
Inflammation		1.57		1.24
Atrophy		1.22		0.99
Ectopic parotid gland		0.52		0.58

<b>SUBMANDIBULAR GL. 1223</b>		<b>1212</b>	
Atrophy	1.47		2.39
Lymphoid cell foci	1.23		1.73
Interstitial fibrosis	1.06		1.32
Inflammation	0.98		0.41
<b>URINARY BLADDER 2138</b>		<b>2129</b>	
Lymphoid cell foci	6.83		4.79
Inflammation	3.98		0.85
Urothelial hyperplasia	1.54		0.61
Luminal distention	1.31		0.33
<b>KIDNEYS 2210</b>		<b>2183</b>	
Chronic prog. Nephropathy	56.52		21.3
Lymphoid cell foci	51.72		50.62
Tubular pigmentation	22.31		38.62
Tubular dilation	19.82		19.7
Tubular casts	18.51		20.98
Tubular basophilia	14.3		17.91
Tubular atrophy	13.62		16.08
Pelvic mineralization	12.04		26.52
Glomerulosclerosis	9.32		4.35
Cort. Med. Mineralization	8.96		42.56
Pelvic calculi	8.19		22.63
Pyelitis	6.7		4.76
Cortical mineralization	5.34		23.18
Urothelial hyperplasia	5.16		11.04
Medullary Mineralization	3.98		7.15
<b>SKIN 2075</b>		<b>2084</b>	
Atrophy of adnexum	5.93		5.85
Pododermatitis	3.13		0.05
Inflammation	2.94		2.26
Epidermoid cyst	1.93		0.29
Abscess	0.92		0.05
Hyperkeratosis	0.72		2.4
Follicular keratosis	0.72		0.58
Acanthosis	0.48		0.82
<b>TESTES 2228</b>			
Tubular atrophy	24.33		
Periarteritis/arteritis	12.39		
Mineralization	6.01		
Leydig cell hyperplasia	4.13		
Sperm stasis	1.26		
<b>EPIDIDYMIDES 2080</b>			
Aspermia	10.82		
Oligospermia	7.74		
Lymphoid cell foci	5.05		
Segmental change	4.71		
Vacuolization	2.55		
Atrophy	1.06		
<b>PROSTATE 2218</b>			
Inflammation	29.44		
Concretions	8.52		
Alveolar atrophy	7.8		
Lymphoid cell foci	5.37		
Hyperplasia	4.69		

<b>SEMINAL VESICLES</b>	<b>1995</b>		
Atrophy	13.13		
Inflammation	7.62		
Dilated acini	6.52		
Reduced secretions	2.91		
Reduced size	2.51		
<b>MAMMARY GLANDS</b>	<b>1110</b>	<b>2081</b>	
Concretion	11.08		12.59
Cystic change	4.05		28.35
Secretion	3.24		10.91
Acinar hyperplasia	2.61		20.04
Galactocele	0.36		8.46
Alveolar/ductal degeneration	0		4.76
<b>OVARIES</b>		<b>2134</b>	
Cyst(s)			10.97
Pigment deposition			6.79
Atrophy			5.01
Interstitial cell hyperplasia			4.92
Sertoli cell hyperplasia			3.56
<b>UTERUS</b>		<b>2193</b>	
Stromal proliferation			11.81
Distended lumen			8.76
Glandular hyperplasia			8.66
Squamous hyperplasia			5.7
Pigment deposition			5.65
Endometrial fibrosis			4.15
Congestion			3.19
<b>CERVIX</b>		<b>269</b>	
Collagenosis/fibrosis			3.35
Squamous cell hyperplasia			0.37
<b>VAGINA</b>		<b>636</b>	
Mucification			3.14
Abscess(es)			1.42
Dilated lumen			1.26
Inflammation			1.1
<b>BONE MARROW</b>	<b>1677</b>	<b>1670</b>	
Hemopoietic activity	5.31		5.57
Increased granulopoiesis	5.13		5.39
Atrophy	1.31		0.66
Decreased erythropoiesis	1.01		1.62
Necrosis	0.89		1.2
Myelofibrosis	0.78		0.66
Increased erythropoiesis	0.66		1.44
<b>MESENTERIC L. N.</b>	<b>2074</b>	<b>2058</b>	
Pigment deposition	22.28		24.83
Histiocytosis	11.96		15.21
Sinosoidal cysts	7.96		5.54
Congestion	7.33		4.23
Lymphoid hyperplasia	6.94		5.73
Erythrophagocytosis	3.33		2.92

<b>MANDIBULAR L. N.</b>	<b>1845</b>		<b>1867</b>
Sinosoidal cysts		16.42	12.64
Lymphoid hyperplasia		10.46	8.52
Hyperemia		8.67	6.00
Plasmacytosis		7.05	7.45
Hemosiderin		6.45	12.0
Histiocytosis		1.84	2.46
<b>OTHER L. N.</b>	<b>435</b>		<b>393</b>
Sinus dilation		26.67	8.65
Lymphoid hyperplasia		20.92	21.88
Congestion		20.69	12.47
Pigment deposition		13.79	20.36
Histiocytosis		8.05	8.91
Erythrophagocytosis		8.05	3.82
<b>THYMUS</b>	<b>1940</b>		<b>2067</b>
Involution		14.79	11.03
Medullary cysts		12.01	33.91
Congestion		4.85	3.0
Hemorrhage		1.91	0.97
Epithelial hyperplasia		1.44	5.32
<b>SPLEEN</b>	<b>2211</b>		<b>2194</b>
Increased hemosiderin		24.51	28.30
Increased erythropoiesis		17.96	22.93
Increased hemopoiesis		17.82	18.14
Congestion		8.14	8.02
Increased granulopoiesis		3.62	5.65
Lymphoid hyperplasia		2.17	2.23
<b>TONGUE</b>	<b>1185</b>		<b>1179</b>
Inflammation		2.95	4.33
Lymphoid cell foci		1.94	2.37
Periarteritis/arteritis		1.94	1.7
Hyperkeratosis		0.93	1.53
Myofiber atrophy		0.17	1.7
<b>NASAL TURBINATES</b>	<b>199</b>		<b>207</b>
Inflammation		7.54	5.31
Dilated glands		7.54	3.86
Lymphoid hyperplasia		1.01	0
<b>JOINTS</b>	<b>330</b>		<b>300</b>
Arthropathy		14.85	15.0
Arthritis		0.61	1.0
<b>BONE</b>	<b>1416</b>		<b>1357</b>
Cartilage degeneration		14.76	15.18
Aseptic necrosis		3.18	4.35
Fibro-osseous lesion		1.41	1.62
<b>SKELETAL MUSCLE</b>	<b>2029</b>		<b>2020</b>
Atrophy		27.85	12.87
Inflammation		4.48	1.53
Lymphoid cell foci		1.18	2.13
<b>BODY CAVITIES</b>	<b>197</b>		<b>212</b>
Fat necrosis		28.43	34.91
Inflammation		2.54	2.83
Periarteritis/arteritis		2.03	0
<b>ADIPOSE TISSUE</b>	<b>21</b>		<b>15</b>
Nodular fat necrosis		52.38	46.67