

Reproductive Toxicology

Historical Control Data in Golden Syrian Hamsters

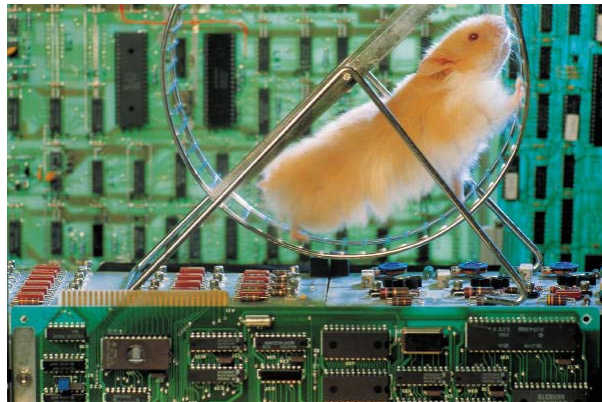


TABLE OF CONTENTS

Crl:LVG(SYR) Golden Syrian Hamster

<u>HCD</u>¹	<u>Date Range</u>	<u>Page</u>
Male Mating/Fertility	1995 - 2017	3
Estrous Cycling	2012 - 2017	7
Female Mating/Fertility	1995 - 2017	8
DG 14 and 15 Maternal Reproductive Indices	1993 - 2017	9
DG 14 and 15 Fetal Gross External Alterations	1993 - 2017	13
DG 14 and 15 Fetal Soft Tissue Alterations	1998 - 2017	14
DG 14 and 15 Fetal Skeletal Alterations	1993 - 2017	15
DG 14 and 15 Fetal Ossification Site Averages	1993 - 2013	19

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¹ Additional HCD endpoints and years are available upon request.

MALE MATING/FERTILITY
Cr1:LVG(SYR) GOLDEN SYRIAN HAMSTERS

HAMSTERS EVALUATED	97			
	MEAN	MINIMUM	MAXIMUM	NO. STUDIES INCLUDED
DAYS IN COHABITATION	3.0	2.7	3.5	5
HAMSTERS THAT MATED	19	14	25	5
	97.4	93.0	100.0	5
FERTILITY INDEX ¹	17	14	22	5
	19	15	25	5
	89.6	80.0	93.8	5
HAMSTERS WITH CONFIRMED MATING DATES	19	14	25	5
HAMSTERS MATED WITH FEMALE				
DAYS 1-7	18	14	24	5
	95.0	92.0	100.0	5
DAYS 8-14	1	0	2	5
	3.6	0.0	8.0	5
HAMSTERS PREGNANT /	16	14	22	5
HAMSTERS IN COHABITATION	18	15	25	5
	90.6	87.5	93.8	5

¹ Number of pregnancies/number of hamsters that mated

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MALE REPRODUCTIVE ORGAN WEIGHTS AND RATIOS
Ctrl:LVG(SYR) GOLDEN SYRIAN HAMSTERS

TOTAL HAMSTERS EVALUATED	72			
	MEAN	MINIMUM	MAXIMUM	NO. STUDIES INCLUDED
TERMINAL BODY WEIGHT	147.1	136.5	156.6	5
TESTIS				
LEFT	1.6685	1.2750	1.8394	5
RIGHT	1.6689	1.2495	1.8548	5
EPIDIDYMIS				
LEFT	0.6966	0.4725	0.7904	5
RIGHT	0.7020	0.4758	0.7824	5
CAUDA EPIDIDYMIS LEFT	0.3663	0.2749	0.4061	5
PROSTATE	0.2392	0.1774	0.3184	5
SEMINAL VESICLES				
WITH FLUID	1.9787	1.2382	2.4269	5
WITHOUT FLUID	0.8316	0.4976	0.9955	5
RATIO (%) ORG. WTS. TO BODY WTS.				
TESTIS (% TBW)				
LEFT	1.130	0.930	1.193	5
RIGHT	1.131	0.910	1.207	5
EPIDIDYMIS (% TBW)				
LEFT	0.470	0.344	0.505	5
RIGHT	0.477	0.346	0.538	5
CAUDA EPIDIDYMIS LEFT (% TBW)	0.248	0.201	0.264	5
PROSTATE (% TBW)	0.160	0.120	0.206	5
SEMINAL VESICLES				
WITH FLUID (% TBW)	1.3376	0.9012	1.5550	5
WITHOUT FLUID (% TBW)	0.564	0.365	0.654	5

ALL WEIGHTS ARE MEASURED IN GRAMS

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SPERM MOTILITY
 Ctrl:LVG(SYR) GOLDEN SYRIAN HAMSTERS

SUMMARY

TOTAL HAMSTERS EVALUATED	97			
	MEAN	MINIMUM	MAXIMUM	NO. STUDIES INCLUDED
<u>VAS DEFERENS (BILATERAL) SPERM MOTILITY</u>				
MOTILE PERCENT	76.6	66.3	87.0	4
<u>CAUDA EPIDIDYMAL SPERM MOTILITY</u>				
MOTILE PERCENT	81.5	81.5	81.5	1
<u>CAUDA EPIDIDYMAL SPERM COUNT</u>				
CONCENTRATION	619.8	619.8	619.8	1
DENSITY	1997.1	1385.3	2593.6	4

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SPERM MORPHOLOGY
Cr1:LVG(SYR) GOLDEN SYRIAN HAMSTERS

SUMMARY

TOTAL HAMSTERS EVALUATED	37			
	MEAN	MINIMUM	MAXIMUM	NO. STUDIES INCLUDED
NORMAL	343.95	190.5	497.4	2
PERCENT ABNORMAL	2.9	0.5	5.3	2
DETACHED HEAD	3	0.1	5.9	2
NO HEAD	2.3	0	4.6	2
BROKEN FLAGELLUM	0.05	0	0.1	2
NO HOOK	0	0	0	2
EXCESSIVE HOOK	0	0	0	2
AMORPHOUS	0	0	0	2
PIN HEAD	0	0	0	2
TWO HEADS & TAILS	0	0	0	2
SHORT SPERM HEAD	0	0	0	2
BANANA	0	0	0	2
COILED FLAGELLUM	0.75	0.1	1.4	2
BENT FLAGELLUM	0.45	0	0.9	2
BENT FLAGELLUM TIP	0.15	0	0.3	2
OTHER	0	0	0	2

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FEMALE ESTROUS CYCLING
HISTORICAL CONTROL DATA
CrI:LVG(SYR) HAMSTERS

SUMMARY

TOTAL HAMSTERS EVALUATED	74			
	MEAN	MINIMUM	MAXIMUM	NO. STUDIES INCLUDED
PREDOSE ESTROUS CYCLING				
ESTROUS STAGES/14 DAYS	3.0	2.5	3.5	5
HAMSTERS WITH 6 OR MORE CONSECUTIVE DAYS OF DIESTRUS	0.0	0.0	0.0	5
HAMSTERS WITH 6 OR MORE CONSECUTIVE DAYS OF ESTRUS	0.0	0.0	0.0	5
PRECOHABITATION ESTROUS CYCLING				
ESTROUS STAGES/14 DAYS	3.3	3.0	3.5	5
HAMSTERS WITH 6 OR MORE CONSECUTIVE DAYS OF DIESTRUS	0.3	0.0	1.0	5
HAMSTERS WITH 6 OR MORE CONSECUTIVE DAYS OF ESTRUS	0.2	0.0	1.0	5

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FEMALE MATING AND FERTILITY
HISTORICAL CONTROL DATA
Ctrl:LVG(SYR) HAMSTERS

SUMMARY

TOTAL HAMSTERS EVALUATED	74			
				NO. STUDIES
	MEAN	MINIMUM	MAXIMUM	INCLUDED
DAYS IN COHABITATION	2.9	2.6	3.5	5
HAMSTERS THAT MATED	20	15	25	5
	100.0	100.0	100.0	5
FERTILITY INDEX ¹	18	14	22	5
	20	15	25	5
	89.8	80.0	94.1	5
HAMSTERS WITH CONFIRMED MATING DATES	19	14	25	5
HAMSTERS MATED BY FIRST MALE DAYS 1-7	18	14	24	5
	95.0	92.0	100.0	5
DAYS 8-14	1	0	2	5
	3.6	0.0	8.0	5
HAMSTERS PREGNANT/HAMSTERS IN COHABITATION	17	14	22	5
	19	15	25	5
	92.3	88.0	94.1	4

¹ Number of pregnancies/number of hamsters
that mated

Updated 03 March 2019

REPRODUCTIVE INDICES
Ctrl:LVG(SYR) HAMSTERS
GESTATION DAY 14 CAESAREAN-SECTION

	FULL STUDIES			DOSE RANGE STUDIES		
NO. OF STUDIES INCLUDED	11			4		
NO. OF HAMSTERS TESTED	245			26		
NO. OF HAMSTERS PREGNANT	209			23		
NO. FOUND DEAD	1			0		
NO. ABORTED	0			0		
NO. DELIVERED	3			0		
CAESAREAN-SECTIONED ON GD 14	206			23		
NO. OF HAMSTERS WITH SINGLE CONCEPTUS LITTER						
LIVE:	0			0		
RESORBED:	0			0		
ABORTED:	0			0		
	MEAN	MIN	MAX	MEAN	MIN	MAX
PREGNANT (%)	86.7	62.5	96.0	88.5	83.3	100.0
CORPORA LUTEA	16.5	12.9	19.6	15.7	12.0	17.3
IMPLANTATIONS	15.7	11.2	19.3	15.4	11.4	17.1
PREIMPLANTATION LOSS (%)	3.5	0.4	8.8	2.0	0.0	6.0
LITTER SIZES						
LIVE FETUSES	15.0	10.5	18.8	15.0	11.0	16.7
DEAD FETUSES	0.0	0.0	0.0	0.0	0.0	0.0
TOTAL RESORPTIONS	0.6	0.1	1.2	0.4	0.3	0.6
EARLY RESORPTIONS	0.5	0.1	1.0	0.4	0.2	0.4
LATE RESORPTIONS	0.1	0.0	0.7	0.1	0.0	0.2
POSTIMPLANTATION LOSS (%)	3.4	0.9	5.7	2.8	1.9	3.5
DAMS WITH ANY RESORPTIONS (%)	38.9	13.0	54.5	39.0	33.3	42.8
DAMS WITH ALL CONCEPTUSES RESORBED (%)	0.2	0.0	1.0	0.0	0.0	0.0
DAMS WITH VIABLE FETUSES (%)	98.9	93.3	100.0	100.0	100.0	100.0

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REPRODUCTIVE INDICES
 Ctrl:LVG(SYR) HAMSTERS
 GESTATION DAY 14 CAESAREAN-SECTION

NO. OF STUDIES INCLUDED	FULL STUDIES 11			DOSE RANGE STUDIES 4		
	MEAN	MIN	MAX	MEAN	MIN	MAX
SEX RATIO (% MALES/LITTER)	43.4	36.1	49.3	46.2	39.0	53.0
LIVE FETAL BODY WEIGHTS GRAMS/LITTER:	1.84	1.71	1.97	1.90	1.87	1.93
MALE FETUSES:	1.87	1.77	1.99	1.93	1.91	1.95
FEMALE FETUSES:	3.56	1.68	19.33	1.88	1.83	1.97
DAMS WITH NORMAL PLACENTAE (%)	3.5	0.9	5.8	2.7	1.9	3.4

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REPRODUCTIVE INDICES
 Ctrl:LVG(SYR) HAMSTERS
 GESTATION DAY 15 CAESAREAN-SECTION

	FULL STUDIES			DOSE RANGE STUDIES		
NO. OF STUDIES INCLUDED	3			--		
NO. OF HAMSTERS TESTED	69			--		
NO. OF HAMSTERS PREGNANT	52			--		
NO. FOUND DEAD	1			--		
NO. ABORTED	1			--		
NO. DELIVERED	28			--		
CAESAREAN-SECTIONED ON GD 15	44			--		
NO. OF HAMSTERS WITH SINGLE CONCEPTUS LITTER						
LIVE:	0			--		
RESORBED:	0			--		
ABORTED:	0			--		
	MEAN	MIN	MAX	MEAN	MIN	MAX
PREGNANT (%)	76.8	71.4	82.4	--	--	--
CORPORA LUTEA	15.1	14.8	15.3	--	--	--
IMPLANTATIONS	14.7	13.8	15.2	--	--	--
PREIMPLANTATION LOSS (%)	1.1	1.0	1.3	--	--	--
LITTER SIZES						
LIVE FETUSES	14.3	13.4	15.0	--	--	--
DEAD FETUSES	0.1	0.0	0.2	--	--	--
TOTAL RESORPTIONS	0.4	0.2	0.7	--	--	--
EARLY RESORPTIONS	0.4	0.2	0.7	--	--	--
LATE RESORPTIONS	0.0	0.0	0.0	--	--	--
POSTIMPLANTATION LOSS (%)	4.0	0.9	7.1	--	--	--
DAMS WITH ANY RESORPTIONS (%)	14.2	5.9	25.0	--	--	--
DAMS WITH ALL CONCEPTUSES RESORBED (%)	2.4	0.0	7.1	--	--	--
DAMS WITH VIABLE FETUSES (%)	100.0	100.0	100.0	--	--	--

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REPRODUCTIVE INDICES
Cr1:LVG(SYR) HAMSTERS
GESTATION DAY 15 CAESAREAN-SECTION

NO. OF STUDIES INCLUDED	FULL STUDIES 3			DOSE RANGE STUDIES --		
	MEAN	MIN	MAX	MEAN	MIN	MAX
SEX RATIO (% MALES/LITTER)	50.0	47.5	54.9	--	--	--
LIVE FETAL BODY WEIGHTS GRAMS/LITTER:	2.64	2.60	2.66	--	--	--
MALE FETUSES:	2.67	2.63	2.70	--	--	--
FEMALE FETUSES:	2.60	2.57	2.63	--	--	--
DAMS WITH NORMAL PLACENTAE (%)	3.5	3.5	3.5	--	--	--

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FETAL EXTERNAL ABNORMALITIES
GOLDEN SYRIAN HAMSTERS [CrI:LVG(SYR)]
GESTATION DAY 14/15 CAESAREAN-SECTION

PERIOD: 1993 THROUGH 2017

	FULL STUDIES	DOSE-RANGE STUDIES
NO. OF STUDIES INCLUDED	5	1
NO. LITTERS EVALUATED	87	7
NO. FETUSES EVALUATED	1311	116

ABNORMALITIES			RANGE/STUDY			RANGE/STUDY		
			N	N	%	N	N	%
BODY	: Rachischisis	L	1	0-1	(0-6.7)	---	---	---
		F	1	0-1	(0-0.4)	---	---	---
EYE(S)	: Bulge, depressed	L	1	0-1	(0-5.0)	1	0-1	(0-14.3)
		F	1	0-1	(0-0.4)	1	0-1	(0-0.09)
LIMB(S)	: Malrotated	L	1	0-1	(0-7.7)	---	---	---
		F	2	0-2	(0-1.0)	---	---	---
TAIL	: Short	L	1	0-1	(0-5.3)	---	---	---
		F	1	0-1	(0-0.3)	---	---	---

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All values are based on studies with findings.

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FETAL VISCERAL ABNORMALITIES
GOLDEN SYRIAN HAMSTERS [CrI:LVG(SYR)]
GESTATION DAY 14/15 CAESAREAN-SECTION

PERIOD: 1998 THROUGH 2017

	FULL STUDIES	DOSE-RANGE STUDIES
NO. OF STUDIES INCLUDED	1	---
NO. LITTERS EVALUATED	20	---
NO. FETUSES EVALUATED	128	---

	ABNORMALITIES	N	RANGE/STUDY			RANGE/STUDY		
			N	%		N	%	
SPLEEN	: Large	L	1	0-1	(0-5.0)	---	---	---
		F	1	0-1	(0-0.8)	---	---	---

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All values are based on studies with findings.

Updated 03 March 2019

FETAL SKELETAL ABNORMALITIES
GOLDEN SYRIAN HAMSTERS [CrI:LVG(SYR)]
GESTATION DAY 14/15 CAESAREAN-SECTION

PERIOD: 1993 THROUGH 2017

			NO. OF STUDIES INCLUDED		8		
			NO. LITTERS EXAMINED		120		
			NO. FETUSES EXAMINED		908		
SKULL			ABNORMALITIES		RANGE/STUDY		
					N	N	
		Eye Socket				%	
			: Small	L	1	0-1	(0-14.3)
				F	1	0-1	(0-1.7)
		Frontals					
			: Incompletely ossified	L	6	0-2	(0-33.3)
				F	7	0-3	(0-3.8)
		Hyoid					
			: Body, not ossified	L	4	0-2	(0-33.3)
				F	4	0-2	(0-3.8)
		Parietals					
			: Not ossified	L	7	0-4	(0-57.1)
				F	8	0-5	(0-8.3)
			: Incompletely ossified	L	2	0-2	(0-10.5)
				F	3	0-3	(0-1.9)
		Interparietals					
			: Not ossified	L	10	0-5	(0-71.4)
				F	15	0-9	(0-15.0)
			: Incompletely ossified	L	2	0-2	(0-10.5)
				F	3	0-3	(0-1.9)
		Squamosal					
			: Incompletely ossified	L	11	0-5	(0-71.4)
				F	26	0-12	(0-23.1)
	Supraoccipitals						
		: Incompletely ossified	L	2	0-1	(0-16.7)	
			F	2	0-1	(0-1.9)	
	Zygomatics						
		: Incompletely ossified	L	11	0-5	(0-71.4)	
			F	26	0-12	(0-23.1)	

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FETAL SKELETAL ABNORMALITIES
GOLDEN SYRIAN HAMSTERS [CrI:LVG(SYR)]
GESTATION DAY 14/15 CAESAREAN-SECTION

VERTEBRAE	ABNORMALITIES		RANGE/STUDY		
			N	N	%
Cervical	: Cervical rib present at 7th vertebra	L	5	0-2	(0-10.0)
		F	7	0-3	(0-2.0)
	: Arch, incompletely ossified	L	8	0-4	(0-66.7)
		F	14	0-9	(0-17.3)
	: Arch, misshapen	L	4	0-3	(0-23.1)
		F	6	0-4	(0-3.8)
	: Centrum, incompletely ossified	L	5	0-2	(0-33.3)
		F	6	0-3	(0-3.8)
	: Centrum, not ossified	L	4	0-2	(0-16.7)
		F	5	0-3	(0-1.9)
	: Centrum, absent	L	1	0-1	(0-7.7)
		F	1	0-1	(0-1.0)
	: Arch, incompletely ossified	L	2	0-1	(0-16.7)
		F	2	0-1	(0-1.9)
	: Arch, fused	L	1	0-1	(0-7.7)
		F	1	0-1	(0-1.0)
	: Arch, small	L	1	0-1	(0-7.7)
		F	1	0-1	(0-1.0)
	: Hemivertebra	L	1	0-1	(0-7.7)
		F	1	0-1	(0-1.0)
Lumbar	: Centrum, incompletely ossified	L	7	0-3	(0-33.3)
		F	7	0-3	(0-3.8)
	: Centrum, not ossified	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.6)
	: Arch, incompletely ossified	L	3	0-1	(0-16.7)
		F	3	0-1	(0-1.9)
Sacral	: Arch not ossified	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.9)
Caudal	: Centrum, not ossified	L	4	0-2	(0-33.3)
		F	5	0-3	(0-5.8)

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Updated 03 March 2019

FETAL SKELETAL ABNORMALITIES
GOLDEN SYRIAN HAMSTERS [CrI:LVG(SYR)]
GESTATION DAY 14/15 CAESAREAN-SECTION

			ABNORMALITIES		RANGE/STUDY	
					N	N
RIB(S)						
	: T14, short	L	30	0-10	(0-100.0)	
		F	66	0-22	(0-42.3)	
	: T14, full	L	2	0-1	(0-16.7)	
		F	3	0-2	(0-3.8)	
	: Absent	L	1	0-1	(0-7.7)	
		F	1	0-1	(0-1.0)	
	: Branched	L	1	0-1	(0-7.7)	
		F	1	0-1	(0-1.0)	
	: Fused	L	1	0-1	(0-7.7)	
		F	1	0-1	(0-1.0)	
	: Malpositioned	L	1	0-1	(0-7.7)	
		F	1	0-1	(0-1.0)	
	: Misshapen	L	1	0-1	(0-7.7)	
F		1	0-1	(0-1.0)		
STERNUM						
Sternebrae						
	: 1st, incompletely ossified	L	41	0-19	(0-100.0)	
		F	149	0-104	(0-67.5)	
	: 2nd, incompletely ossified	L	14	0-8	(0-34.8)	
		F	17	0-11	(0-7.3)	
	: 2nd, not ossified	L	1	0-1	(0-5.3)	
		F	1	0-1	(0-0.7)	
	: 3rd, incompletely ossified	L	1	0-1	(0-5.0)	
		F	1	0-1	(0-0.7)	
	: Two or more, fused	L	8	0-4	(0-30.8)	
		F	11	0-5	(0-5.0)	
	: One or more, asymmetric	L	22	0-7	(0-35.0)	
		F	26	0-8	(0-5.3)	
	: Not ossified	L	12	0-5	(0-71.4)	
		F	31	0-16	(0-26.7)	
Manubrium						
	: Incompletely ossified	L	13	0-7	(0-100.0)	
		F	83	0-44	(0-75.0)	
	: Not ossified	L	4	0-2	(0-33.3)	
		F	4	0-2	(0-3.8)	
Xiphoid						
	: Not ossified	L	5	0-3	(0-50.0)	
		F	8	0-6	(0-11.5)	

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FETAL SKELETAL ABNORMALITIES
GOLDEN SYRIAN HAMSTERS [CrI:LVG(SYR)]
GESTATION DAY 14/15 CAESAREAN-SECTION

	ABNORMALITIES		RANGE/STUDY		
			N	N	%
FORELIMB(S)	Metacarpal(s)				
	: Not ossified	L	2	0-1	(0-16.7)
		F	2	0-1	(0-1.9)
PELVIS					
	Pubes				
	: Incompletely ossified	L	6	0-2	(0-33.3)
		F	6	0-2	(0-3.8)
	: Unossified	L	1	0-1	(0-5.3)
		F	2	0-2	(0-1.3)
	Ischium				
	: Incompletely ossified	L	6	0-2	(0-33.3)
		F	6	0-2	(0-3.8)
	: Unossified	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.6)
HINDLIMB(S)					
	Metatarsal(s)				
	: Not ossified	L	6	0-3	(0-50.0)
		F	9	0-5	(0-9.6)

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SUMMARY OF FETAL OSSIFICATION SITES
SKELETAL AVERAGES
CrI:LVG(SYR) GOLDEN SYRIAN HAMSTERS
DAY 14 OR 15 CAESAREAN-SECTION

PERIOD: 1993 - 2013

	DAY 14 CAESAREAN-SECTION	DAY 15 CAESAREAN-SECTION
NO. STUDIES INCLUDED	2	1
NO. LITTERS EXAMINED	42	20
NO. FETUSES EXAMINED	298	139

SKELETAL AVERAGES	FETUS / LITTER		FETUS / LITTER	
	MEAN	RANGE	MEAN	RANGE
HYOID	0.99	(0.98-0.99)	1.00	---
VERTEBRAE:				
CERVICAL	7.00	--	7.00	---
THORACIC	13.21	(13.13-13.27)	13.18	---
LUMBAR	5.78	(5.72-5.85)	5.81	---
SACRAL	3.00	--	3.00	---
CAUDAL	2.92	(2.43-3.32)	5.72	---
RIBS (pairs)	13.16	(13.09-13.22)	13.14	---
STERNUM				
MANUBRIUM	0.98	(0.96-0.99)	1.00	---
STERNAL CENTERS	2.86	(2.73-2.96)	3.90	---
XIPHOID	0.96	--	1.00	---
FORELIMB ^a				
CARPALS	0.00	--	0.00	---
METACARPALS	2.96	(2.90-3.01)	3.94	---
DIGITS	5.00	--	5.00	---
PHALANGES	5.00	--	5.14	---
HINDLIMB ^a				
TARSALS	0.00	--	0.00	---
METATARSALS	2.69	(2.44-2.90)	3.98	---
DIGITS	5.00	--	5.00	---
PHALANGES	5.00	--	5.00	---

a. Calculated as average per limb

Updated 03 March 2019