

Experiment Number: 20725 - 03

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS
ABRIDGED) (a)**

Date Report Requested: 04/12/2016

Test Type: CHRONIC

2,3-Butanedione

Time Report Requested: 16:27:54

Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 431-03-8

First Dose M/F: 08/17/09 / 08/17/09

Species/Strain: RATS/Wistar Han

Lab: BNW

F1_RE

NTP Study Number: C20725
Lock Date: 10/11/2012
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: 01/15/2016

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2,3-Butanedione

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CAS Number: 431-03-8

First Dose M/F: 08/17/09 / 08/17/09

Species/Strain: RATS/Wistar Han

Lab: BNW

Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	12	11	15	18
Natural Death	2	2	2	10
Survivors				
Moribund Sacrifice		1		
Terminal Sacrifice	36	36	33	22
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Carcinoma				1 (2%)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Schwannoma Malignant, Metastatic, Heart		1 (2%)		
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Schwannoma Malignant, Metastatic, Heart		1 (2%)		
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Carcinoid Tumor Benign		1 (2%)		
Schwannoma Malignant, Metastatic, Heart		1 (2%)		
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Leiomyoma	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Hemangioma	1 (2%)			
Hepatocellular Adenoma		1 (2%)		
Schwannoma Malignant, Metastatic, Heart		1 (2%)		
Mesentery	(5)	(4)	(3)	(2)
Carcinosarcoma, Metastatic, Prostate	1 (20%)			
Hemangiosarcoma		1 (25%)		
Fat, Liposarcoma, Metastatic, Kidney		1 (25%)		
Oral Mucosa	(1)	(1)	(0)	(0)
Squamous Cell Carcinoma	1 (100%)	1 (100%)		

a - Number of animals examined microscopically at site and number of animals with lesion

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Species/Strain: RATS/Wistar Han

Lab: BNW

Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
Pancreas	(50)	(50)	(50)	(50)
Acinus, Carcinoma, Metastatic, Prostate	1 (2%)			
Salivary Glands	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)		
Stomach, Forestomach	(50)	(50)	(50)	(50)
Sarcoma			1 (2%)	
Squamous Cell Carcinoma			1 (2%)	
Squamous Cell Papilloma		1 (2%)	1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)
Schwannoma Malignant, Metastatic, Heart		1 (2%)		
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Neural Crest Tumor, Metastatic, Ear			1 (2%)	
Schwannoma Malignant		2 (4%)	1 (2%)	
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	2 (4%)	2 (4%)	1 (2%)	1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	1 (2%)	3 (6%)	1 (2%)	3 (6%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Parathyroid Gland	(49)	(46)	(49)	(47)
Adenoma	1 (2%)			
Bilateral, Adenoma		1 (2%)		
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	9 (18%)	14 (28%)	9 (18%)	5 (10%)
Pars Intermedia, Adenoma	2 (4%)	1 (2%)		1 (2%)
Pars Nervosa, Schwannoma Malignant				1 (2%)
Thyroid Gland	(50)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma	1 (2%)			

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Species/Strain: RATS/Wistar Han

Lab: BNW

Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
C-cell, Adenoma	5 (10%)	5 (10%)	3 (6%)	1 (2%)
C-cell, Adenoma, Multiple			1 (2%)	
C-cell, Carcinoma		1 (2%)	1 (2%)	
Follicular Cell, Adenoma	2 (4%)	1 (2%)	2 (4%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Prostate	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Carcinosarcoma	1 (2%)			
Seminal Vesicle	(50)	(50)	(50)	(50)
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma	3 (6%)	3 (6%)		1 (2%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(6)	(4)	(9)	(7)
Lymph Node, Bronchial	(41)	(46)	(43)	(42)
Lymph Node, Mandibular	(48)	(44)	(49)	(48)
Squamous Cell Carcinoma, Metastatic, Skin				1 (2%)
Lymph Node, Mediastinal	(42)	(47)	(47)	(47)
Hemangiosarcoma		1 (2%)		
Schwannoma Malignant, Metastatic, Thymus			1 (2%)	
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Hemangioma			1 (2%)	1 (2%)
Hemangiosarcoma	2 (4%)		1 (2%)	
Schwannoma Malignant, Metastatic, Heart		1 (2%)		

a - Number of animals examined microscopically at site and number of animals with lesion

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Species/Strain: RATS/Wistar Han

Lab: BNW

Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)			
Thymus	(47)	(48)	(48)	(48)
Schwannoma Malignant			1 (2%)	
Thymoma Benign	1 (2%)		1 (2%)	

INTEGUMENTARY SYSTEM

Mammary Gland	(12)	(9)	(14)	(22)
Carcinoma	1 (8%)			
Skin	(50)	(50)	(50)	(50)
Trichoepithelioma		1 (2%)		
Epidermis, Basal Cell Carcinoma		1 (2%)		
Epidermis, Keratoacanthoma	3 (6%)	2 (4%)	1 (2%)	
Epidermis, Pilomatrixoma			1 (2%)	
Epidermis, Squamous Cell Carcinoma			1 (2%)	1 (2%)
Epidermis, Squamous Cell Papilloma		1 (2%)		
Sebaceous Gland, Adenoma	1 (2%)			
Subcutaneous Tissue, Fibrosarcoma				1 (2%)
Subcutaneous Tissue, Fibrous Histiocytoma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Hemangioma			1 (2%)	
Subcutaneous Tissue, Myxoma	1 (2%)			
Subcutaneous Tissue, Schwannoma Malignant				1 (2%)

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(6)	(3)	(4)	(6)
Hemangiosarcoma			1 (25%)	
Squamous Cell Carcinoma, Metastatic, Oral Mucosa		1 (33%)		

NERVOUS SYSTEM

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
Brain	(50)	(50)	(50)	(50)
Glioma Malignant	1 (2%)	1 (2%)	1 (2%)	
Granular Cell Tumor Benign	3 (6%)	2 (4%)	2 (4%)	1 (2%)
Granular Cell Tumor Malignant	1 (2%)			
Squamous Cell Carcinoma, Metastatic, Oral Mucosa		1 (2%)		
Peripheral Nerve	(6)	(1)	(3)	(6)
Spinal Cord	(6)	(1)	(3)	(6)

RESPIRATORY SYSTEM

Larynx	(50)	(50)	(50)	(50)
Lung	(50)	(49)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)			1 (2%)
Carcinosarcoma, Metastatic, Prostate	1 (2%)			
Neural Crest Tumor, Metastatic, Ear			1 (2%)	
Mediastinum, Schwannoma Malignant, Metastatic, Heart		1 (2%)		
Nose	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Squamous Cell Carcinoma				3 (6%)
Squamous Cell Papilloma				1 (2%)
Pleura	(0)	(1)	(0)	(0)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Ear	(0)	(0)	(1)	(0)
Neural Crest Tumor			1 (100%)	
Eye	(50)	(50)	(49)	(49)
Schwannoma Malignant, Metastatic, Harderian Gland		1 (2%)		
Retina, Melanoma Malignant		1 (2%)		
Harderian Gland	(50)	(50)	(50)	(50)
Schwannoma Malignant		1 (2%)		

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
Lacrimal Gland	(0)	(0)	(0)	(1)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Liposarcoma		1 (2%)		
Ureter	(0)	(1)	(0)	(0)
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)	1 (2%)		
Lymphoma Malignant	3 (6%)		3 (6%)	1 (2%)
Mesothelioma Malignant	1 (2%)	2 (4%)	1 (2%)	2 (4%)

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* Number of animals with any tissue examined microscopically

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Lab: BNW

Wistar Han RATS MALE

Control

12.5 ppm

25 ppm

50 ppm

Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	35	36	30	22
Total Primary Neoplasms	53	57	39	27
Total Animals with Benign Neoplasms	27	30	22	16
Total Benign Neoplasms	39	41	24	16
Total Animals with Malignant Neoplasms	13	12	13	11
Total Malignant Neoplasms	14	16	13	11
Total Animals with Metastatic Neoplasms	1	4	2	1
Total Metastatic Neoplasms	3	11	3	1
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant			2	
Total Uncertain Neoplasms			2	

*** END OF MALE ***

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors

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Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	15	18	26	15
Natural Death	1	1		4
Survivors				
Moribund Sacrifice				1
Terminal Sacrifice	34	31	24	30
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus		1 (2%)		
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Leiomyosarcoma		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus		2 (4%)		1 (2%)
Cholangioma	3 (6%)	1 (2%)		
Hepatocellular Adenoma		1 (2%)	1 (2%)	
Schwannoma Malignant, Metastatic, Uterus			1 (2%)	
Mesentery	(8)	(10)	(4)	(4)
Adenocarcinoma, Metastatic, Uterus				1 (25%)
Cystadenocarcinoma, Metastatic, Ovary		1 (10%)		
Fat, Schwannoma Malignant, Metastatic, Uterus		1 (10%)		
Pancreas	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus		1 (2%)		
Schwannoma Malignant, Metastatic, Uterus				1 (2%)
Acinus, Adenocarcinoma, Metastatic, Uterus				1 (2%)

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Lab: BNW

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma, Multiple	1 (2%)			
Stomach, Glandular	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus				1 (2%)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus		1 (2%)		1 (2%)
Adenoma	1 (2%)		1 (2%)	1 (2%)
Schwannoma Malignant, Metastatic, Uterus			1 (2%)	
Adrenal Medulla	(50)	(50)	(49)	(50)
Pheochromocytoma Benign	3 (6%)			
Pheochromocytoma Malignant				1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Parathyroid Gland	(46)	(44)	(46)	(42)
Adenoma			1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(50)
Schwannoma Malignant, Metastatic, Harderian Gland		1 (2%)		
Pars Distalis, Adenoma	26 (52%)	24 (48%)	24 (48%)	23 (46%)
Pars Intermedia, Adenoma	1 (2%)			
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Adenoma	2 (4%)	4 (8%)	3 (6%)	3 (6%)
C-cell, Carcinoma	1 (2%)			
Follicular Cell, Adenoma	2 (4%)	4 (8%)	1 (2%)	
Follicular Cell, Carcinoma		1 (2%)		

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Species/Strain: RATS/Wistar Han

Lab: BNW

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
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GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(49)	(50)	(50)	(49)
Ovary	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus				1 (2%)
Cystadenocarcinoma		1 (2%)		
Cystadenoma		1 (2%)		
Granulosa Cell Tumor Malignant		1 (2%)	2 (4%)	
Granulosa-Theca Tumor Malignant	1 (2%)			1 (2%)
Sertoli Cell Tumor Benign				2 (4%)
Thecoma Benign				1 (2%)
Germinal Epithelium, Tubulostromal Adenoma	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Adenocarcinoma	2 (4%)	4 (8%)	2 (4%)	3 (6%)
Adenoma				2 (4%)
Hemangioma				1 (2%)
Leiomyoma		1 (2%)		
Polyp Stromal	9 (18%)	10 (20%)	7 (14%)	13 (26%)
Polyp Stromal, Multiple		3 (6%)		
Sarcoma Stromal			3 (6%)	
Schwannoma Malignant	1 (2%)	2 (4%)	3 (6%)	2 (4%)
Cervix, Granular Cell Tumor Benign		3 (6%)		
Cervix, Hemangioma			1 (2%)	
Cervix, Sarcoma Stromal	1 (2%)			
Cervix, Schwannoma Malignant			1 (2%)	
Cervix, Squamous Cell Carcinoma			1 (2%)	
Serosa, Cystadenocarcinoma, Metastatic, Ovary		1 (2%)		
Vagina	(0)	(1)	(2)	(0)
Granular Cell Tumor Benign		1 (100%)		
Polyp			1 (50%)	

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Lab: BNW

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Schwannoma Malignant, Metastatic, Uterus			1 (50%)	

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(1)	(3)	(2)	(5)
Lumbar, Adenocarcinoma, Metastatic, Uterus		1 (33%)		
Renal, Adenocarcinoma, Metastatic, Uterus		2 (67%)		
Lymph Node, Bronchial	(43)	(44)	(43)	(42)
Lymph Node, Mandibular	(46)	(48)	(45)	(48)
Hemangioma	1 (2%)			
Lymph Node, Mediastinal	(44)	(47)	(48)	(50)
Adenocarcinoma, Metastatic, Uterus				1 (2%)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Hemangiosarcoma	2 (4%)			
Schwannoma Malignant, Metastatic, Uterus		1 (2%)	1 (2%)	
Spleen	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus				1 (2%)
Thymus	(49)	(50)	(49)	(50)

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Adenoma	4 (8%)	3 (6%)	2 (4%)	1 (2%)
Adenoma, Multiple	1 (2%)			
Carcinoma	2 (4%)	4 (8%)	1 (2%)	8 (16%)
Carcinoma, Multiple	2 (4%)			1 (2%)
Fibroadenoma	12 (24%)	10 (20%)	9 (18%)	8 (16%)
Fibroadenoma, Multiple	1 (2%)	3 (6%)	3 (6%)	3 (6%)
Skin	(50)	(50)	(50)	(50)
Subcutaneous Tissue, Adenocarcinoma, Metastatic, Uterus		1 (2%)		
Subcutaneous Tissue, Hibernoma				2 (4%)
Subcutaneous Tissue, Lipoma		1 (2%)	1 (2%)	

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Lab: BNW

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
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MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(3)	(7)	(5)	(5)
Adenocarcinoma, Metastatic, Uterus		2 (29%)		

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Granular Cell Tumor Benign	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Oligodendroglioma Benign	1 (2%)			1 (2%)
Schwannoma Malignant, Metastatic, Harderian Gland		1 (2%)		
Peripheral Nerve	(3)	(5)	(5)	(5)
Trigeminal, Schwannoma Malignant, Metastatic, Harderian Gland		1 (20%)		
Spinal Cord	(3)	(5)	(5)	(5)

RESPIRATORY SYSTEM

Larynx	(50)	(50)	(50)	(50)
Lung	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus		1 (2%)		
Alveolar/Bronchiolar Adenoma				1 (2%)
Schwannoma Malignant, Metastatic, Uterus				1 (2%)
Mediastinum, Adenocarcinoma, Metastatic, Uterus				1 (2%)
Nose	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma				3 (6%)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

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Lab: BNW

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Eye	(50)	(50)	(50)	(50)
Iris, Melanoma Malignant			1 (2%)	
Optic Nerve, Schwannoma Malignant, Metastatic, Harderian Gland		1 (2%)		
Harderian Gland	(50)	(50)	(50)	(50)
Schwannoma Malignant		1 (2%)		

URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Urinary Bladder	(50)	(50)	(50)	(50)
Schwannoma Malignant, Metastatic, Uterus			1 (2%)	1 (2%)

SYSTEMIC LESIONS				
Multiple Organ	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear		1 (2%)		
Lymphoma Malignant	1 (2%)	1 (2%)	3 (6%)	1 (2%)

a - Number of animals examined microscopically at site and number of animals with lesion

* Number of animals with any tissue examined microscopically

Experiment Number: 20725 - 03

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Date Report Requested: 04/12/2016

Test Type: CHRONIC

2,3-Butanedione

Time Report Requested: 16:27:54

Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 431-03-8

First Dose M/F: 08/17/09 / 08/17/09

Species/Strain: RATS/Wistar Han

Lab: BNW

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	40	45	44	40
Total Primary Neoplasms	83	89	73	83
Total Animals with Benign Neoplasms	39	42	38	37
Total Benign Neoplasms	70	72	56	63
Total Animals with Malignant Neoplasms	12	14	17	19
Total Malignant Neoplasms	13	17	17	20
Total Animals with Metastatic Neoplasms		6	3	2
Total Metastatic Neoplasms		20	5	12
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant				
Total Uncertain Neoplasms				

*** END OF REPORT ***

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors