

Experiment Number: 20203 - 03

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

Date Report Requested: 12/20/2013

Test Type: CHRONIC

Green tea extract

Time Report Requested: 09:47:59

Route: GAVAGE

CAS Number: GREENTEAEXTR

First Dose M/F: 07/18/07 / 07/19/07

Species/Strain: RATS/Wistar Han

Lab: BAT

F2_RE

NTP Study Number:	C20203		
Lock Date:	11/12/2010		
Cage Range:	ALL		
Date Range:	ALL		
Reasons For Removal:	25021 TSAC	25020 NATD	25019 MSAC
	25018 DACC		
Removal Date Range:	ALL		
Treatment Groups:	Include ALL		
Study Gender:	Both		
TDMSE Version:	3.0.2.0_001		
PWG Approval Date:	NONE		

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Species/Strain: RATS/Wistar Han

Lab: BAT

Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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Disposition Summary

Animals Initially In Study	60	50	50	60
Early Deaths				
Dosing Accident				2
Moribund Sacrifice	12	7	5	5
Natural Death	3	6	2	19
Survivors				
Natural Death			1	
Terminal Sacrifice	35	37	42	24
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Leiomyosarcoma, Metastatic, Stomach, Forestomach	1 (2%)			
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)	(47)	(49)	(48)
Intestine Small, Ileum	(50)	(48)	(49)	(45)
Intestine Small, Jejunum	(49)	(47)	(48)	(46)
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma				1 (2%)
Mesentery	(3)	(2)	(1)	(1)
Schwannoma Malignant	1 (33%)		1 (100%)	
Oral Mucosa	(1)	(0)	(0)	(0)
Gingival, Squamous Cell Carcinoma	1 (100%)			
Pancreas	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Prostate		1 (2%)		
Leiomyosarcoma, Metastatic, Stomach, Forestomach	1 (2%)			
Salivary Glands	(50)	(50)	(50)	(48)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Leiomyosarcoma	1 (2%)			

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

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Stomach, Glandular	(49)	(50)	(50)	(50)
Tooth	(1)	(1)	(0)	(0)
Odontoma		1 (100%)		

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Adventitia, Aorta, Leiomyosarcoma, Metastatic, Stomach, Forestomach	1 (2%)			
Heart	(50)	(50)	(50)	(50)
Leiomyosarcoma, Metastatic, Stomach, Forestomach	1 (2%)			
Schwannoma Malignant		1 (2%)	1 (2%)	

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			2 (4%)
Osteosarcoma, Metastatic, Bone	1 (2%)			
Adrenal Medulla	(50)	(50)	(50)	(50)
Osteosarcoma, Metastatic, Bone	1 (2%)			
Pheochromocytoma Benign	1 (2%)	1 (2%)	1 (2%)	
Pheochromocytoma Complex		1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		1 (2%)
Parathyroid Gland	(47)	(44)	(49)	(45)
Adenoma				1 (2%)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	16 (32%)	15 (30%)	14 (28%)	10 (20%)
Pars Distalis, Adenoma, Multiple	1 (2%)	2 (4%)	3 (6%)	
Pars Distalis, Carcinoma			2 (4%)	
Pars Intermedia, Adenoma	1 (2%)	2 (4%)		1 (2%)
Pars Nervosa, Adenoma			1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(49)
Bilateral, C-cell, Adenoma		1 (2%)	1 (2%)	

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C-cell, Adenoma	4 (8%)	3 (6%)	5 (10%)	5 (10%)
C-cell, Carcinoma			1 (2%)	
Follicular Cell, Adenoma		3 (6%)	1 (2%)	2 (4%)
Follicular Cell, Adenoma, Multiple			1 (2%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Carcinoma	1 (2%)			
Prostate	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)		
Seminal Vesicle	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Prostate		1 (2%)		
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma	2 (4%)	1 (2%)	1 (2%)	
Interstitial Cell, Adenoma, Multiple		1 (2%)		

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(4)	(0)	(1)	(1)
Lymph Node, Mandibular	(49)	(50)	(50)	(48)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Hemangioma			1 (2%)	
Hemangiosarcoma		1 (2%)		
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma, Metastatic, Lymph Node, Mesenteric		1 (2%)		
Thymus	(49)	(49)	(50)	(50)

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Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Thymoma Benign	2 (4%)	1 (2%)	3 (6%)	

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Fibroadenoma		1 (2%)		
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma	2 (4%)	3 (6%)		
Basosquamous Tumor Malignant		1 (2%)		
Hamartoma	1 (2%)			
Keratoacanthoma	2 (4%)		2 (4%)	
Squamous Cell Carcinoma	1 (2%)			
Squamous Cell Papilloma	1 (2%)		3 (6%)	
Trichoepithelioma		1 (2%)	1 (2%)	
Sebaceous Gland, Adenoma	1 (2%)			
Subcutaneous Tissue, Fibroma	1 (2%)	2 (4%)		
Subcutaneous Tissue, Lipoma	1 (2%)		1 (2%)	
Subcutaneous Tissue, Sarcoma, Metastatic, Bone	1 (2%)			
Subcutaneous Tissue, Schwannoma Malignant	2 (4%)			1 (2%)

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Osteoma	1 (2%)			
Osteosarcoma	1 (2%)			
Joint, Sarcoma	1 (2%)			
Skeletal Muscle	(0)	(0)	(0)	(1)

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Glioma Malignant	1 (2%)		2 (4%)	1 (2%)
Granular Cell Tumor Benign	2 (4%)	2 (4%)	1 (2%)	

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Lab: BAT

Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Meningioma Benign			1 (2%)	
Squamous Cell Carcinoma, Metastatic, Oral Mucosa	1 (2%)			
Peripheral Nerve	(0)	(1)	(0)	(1)
Spinal Cord	(0)	(1)	(0)	(1)

RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma			1 (2%)	
Carcinoma, Metastatic, Prostate		1 (2%)		
Carcinoma, Metastatic, Thyroid Gland			1 (2%)	
Leiomyosarcoma, Metastatic, Stomach, Forestomach	1 (2%)			
Osteosarcoma, Metastatic, Bone	1 (2%)			
Schwannoma Malignant, Metastatic, Skin	1 (2%)			
Squamous Cell Carcinoma, Metastatic, Skin	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Squamous Cell Carcinoma, Metastatic, Oral Mucosa	1 (2%)			
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma, Metastatic, Oral Mucosa	1 (2%)			
Zymbal's Gland	(1)	(0)	(0)	(0)
Carcinoma	1 (100%)			

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
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Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Lipoma			1 (2%)	
Liposarcoma	1 (2%)			
Osteosarcoma, Metastatic, Bone	1 (2%)			
Renal Tubule, Carcinoma		1 (2%)		
Ureter	(1)	(0)	(0)	(0)
Liposarcoma, Metastatic, Kidney	1 (100%)			
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organ	*(50)	*(50)	*(50)	*(50)
Lymphoma Malignant			1 (2%)	
Mesothelioma Malignant	2 (4%)			1 (2%)

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* Number of animals with any tissue examined microscopically

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Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	36	34	32	18
Total Primary Neoplasms	54	47	52	26
Total Animals with Benign Neoplasms	26	31	30	17
Total Benign Neoplasms	40	41	44	23
Total Animals with Malignant Neoplasms	12	6	6	2
Total Malignant Neoplasms	14	6	8	3
Total Animals with Metastatic Neoplasms	6	2	1	
Total Metastatic Neoplasms	16	4	1	
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant				
Total Uncertain Neoplasms				

*** 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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Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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Disposition Summary

Animals Initially In Study	60	50	50	60
Early Deaths				
Dosing Accident			1	3
Moribund Sacrifice	14	12	17	8
Natural Death	10	10	9	35
Survivors				
Terminal Sacrifice	26	28	23	4
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Fibrosarcoma		1 (2%)		
Intestine Large, Cecum	(49)	(49)	(48)	(44)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Intestine Large, Colon	(49)	(49)	(48)	(44)
Adenocarcinoma, Metastatic, Uterus		1 (2%)		
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Intestine Large, Rectum	(49)	(49)	(50)	(45)
Intestine Small, Duodenum	(47)	(48)	(48)	(39)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Serosa, Adenocarcinoma, Metastatic, Uterus		1 (2%)		
Intestine Small, Ileum	(45)	(46)	(47)	(36)
Serosa, Adenocarcinoma, Metastatic, Uterus			1 (2%)	
Intestine Small, Jejunum	(45)	(43)	(45)	(40)
Leiomyosarcoma	1 (2%)	1 (2%)		
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Liver	(50)	(48)	(49)	(46)
Adenocarcinoma, Metastatic, Uterus		2 (4%)	1 (2%)	
Carcinoma, Metastatic, Pancreas				2 (4%)
Cholangioma		1 (2%)		
Hepatocellular Adenoma	1 (2%)	2 (4%)		2 (4%)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Capsule, Adenocarcinoma, Metastatic, Uterus			1 (2%)	

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Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Mesentery	(6)	(3)	(3)	(2)
Adenocarcinoma, Metastatic, Uterus	1 (17%)	3 (100%)	2 (67%)	
Carcinoma, Metastatic, Pancreas				1 (50%)
Hemangiosarcoma	1 (17%)			
Oral Mucosa	(1)	(0)	(0)	(0)
Squamous Cell Carcinoma	1 (100%)			
Pancreas	(50)	(49)	(48)	(44)
Adenocarcinoma, Metastatic, Uterus	1 (2%)	1 (2%)	1 (2%)	
Carcinoma				2 (5%)
Carcinoma, Metastatic, Uterus		1 (2%)		
Salivary Glands	(49)	(48)	(50)	(46)
Stomach, Forestomach	(50)	(50)	(49)	(44)
Adenocarcinoma, Metastatic, Uterus		2 (4%)	1 (2%)	
Leiomyosarcoma		1 (2%)		
Squamous Cell Carcinoma	1 (2%)			
Stomach, Glandular	(50)	(49)	(49)	(44)
Adenocarcinoma, Metastatic, Uterus		2 (4%)		
Carcinoma, Metastatic, Uterus	1 (2%)			
Fibrosarcoma				1 (2%)

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(48)	(50)	(46)
Aorta, Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Heart	(50)	(48)	(50)	(48)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(49)	(49)	(47)
Adenocarcinoma, Metastatic, Uterus			1 (2%)	
Adenoma		2 (4%)	1 (2%)	
Capsule, Adenocarcinoma, Metastatic, Uterus			1 (2%)	
Adrenal Medulla	(50)	(49)	(49)	(47)
Pheochromocytoma Benign	1 (2%)		2 (4%)	

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Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Islets, Pancreatic	(50)	(49)	(48)	(44)
Parathyroid Gland	(47)	(46)	(48)	(44)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	29 (58%)	17 (34%)	12 (24%)	6 (12%)
Pars Distalis, Adenoma, Multiple	3 (6%)	4 (8%)	1 (2%)	2 (4%)
Pars Distalis, Carcinoma			1 (2%)	
Pars Intermedia, Adenoma	1 (2%)		2 (4%)	
Pars Intermedia, Adenoma, Multiple	1 (2%)			
Pars Nervosa, Schwannoma Malignant				1 (2%)
Thyroid Gland	(50)	(49)	(50)	(47)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Bilateral, C-cell, Adenoma		1 (2%)		
C-cell, Adenoma	3 (6%)	3 (6%)	4 (8%)	1 (2%)
C-cell, Carcinoma	1 (2%)			
Follicular Cell, Adenoma	1 (2%)		4 (8%)	1 (2%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(49)	(49)	(50)	(46)
Adenoma			1 (2%)	
Carcinoma			1 (2%)	
Sarcoma			1 (2%)	
Ovary	(50)	(49)	(49)	(44)
Adenocarcinoma, Metastatic, Uterus		1 (2%)	2 (4%)	
Carcinoma, Metastatic, Pancreas				1 (2%)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Oviduct	(1)	(0)	(0)	(0)
Uterus	(50)	(49)	(49)	(44)
Adenocarcinoma	3 (6%)	9 (18%)	5 (10%)	3 (7%)
Adenocarcinoma, Squamous Differentiation				1 (2%)
Adenoma				1 (2%)

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Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Polyp Stromal	2 (4%)	1 (2%)	1 (2%)	3 (7%)
Sarcoma Stromal		1 (2%)	2 (4%)	
Schwannoma Malignant	1 (2%)		2 (4%)	1 (2%)
Cervix, Polyp Stromal	1 (2%)			
Cervix, Sarcoma Stromal	1 (2%)			
Cervix, Schwannoma Malignant				1 (2%)
Vagina	(1)	(2)	(0)	(0)
Adenocarcinoma, Metastatic, Uterus		1 (50%)		
Polyp	1 (100%)			
Sarcoma Stromal		1 (50%)		

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(3)	(1)	(4)	(6)
Iliac, Adenocarcinoma, Metastatic, Uterus	1 (33%)			
Renal, Carcinoma, Metastatic, Uncertain Primary Site				1 (17%)
Lymph Node, Mandibular	(49)	(48)	(50)	(46)
Carcinoma, Metastatic, Zymbal'S Gland			1 (2%)	
Lymph Node, Mesenteric	(50)	(49)	(48)	(45)
Adenocarcinoma, Metastatic, Uterus	1 (2%)	1 (2%)	1 (2%)	
Hemangiosarcoma	1 (2%)			
Spleen	(50)	(49)	(48)	(43)
Adenocarcinoma, Metastatic, Uterus		2 (4%)	2 (4%)	
Carcinoma, Metastatic, Pancreas				1 (2%)
Thymus	(49)	(47)	(50)	(47)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Thymoma Benign	3 (6%)	3 (6%)	5 (10%)	

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(49)	(49)	(47)
Adenoma	2 (4%)		1 (2%)	
Carcinoma	5 (10%)		4 (8%)	

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Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Carcinoma, Multiple	1 (2%)	3 (6%)	1 (2%)	
Fibroadenoma	10 (20%)	7 (14%)	5 (10%)	1 (2%)
Fibroadenoma, Multiple	1 (2%)	1 (2%)		
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma		1 (2%)		
Trichoepithelioma		1 (2%)		
Subcutaneous Tissue, Lipoma		1 (2%)	1 (2%)	
Subcutaneous Tissue, Schwannoma Malignant	2 (4%)			

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(49)
Skeletal Muscle	(0)	(0)	(3)	(2)
Adenocarcinoma, Metastatic, Uterus			2 (67%)	
Carcinoma, Metastatic, Pancreas				2 (100%)
Carcinoma, Metastatic, Zymbal'S Gland			1 (33%)	

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Glioma Malignant		1 (2%)		
Granular Cell Tumor Benign				1 (2%)
Oligodendroglioma Malignant		1 (2%)		
Meninges, Schwannoma Malignant, Metastatic, Pituitary Gland				1 (2%)
Peripheral Nerve	(1)	(2)	(0)	(0)
Spinal Cord	(1)	(2)	(0)	(0)

RESPIRATORY SYSTEM

Lung	(50)	(49)	(50)	(48)
Adenocarcinoma, Metastatic, Uterus	1 (2%)	3 (6%)	2 (4%)	1 (2%)
Carcinoma, Metastatic, Mammary Gland			1 (2%)	
Carcinoma, Metastatic, Pancreas				1 (2%)

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Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Carcinoma, Metastatic, Uterus	1 (2%)			
Sarcoma Stromal, Metastatic, Uterus			2 (4%)	
Nose	(49)	(49)	(50)	(49)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Eye	(48)	(50)	(50)	(49)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Harderian Gland	(48)	(50)	(50)	(49)
Zymbal's Gland	(0)	(0)	(1)	(0)
Carcinoma			1 (100%)	

URINARY SYSTEM

Kidney	(50)	(49)	(49)	(45)
Adenocarcinoma, Metastatic, Uterus			1 (2%)	
Lipoma	1 (2%)			
Capsule, Adenocarcinoma, Metastatic, Uterus			1 (2%)	
Urinary Bladder	(49)	(49)	(49)	(44)
Adenocarcinoma, Metastatic, Uterus			1 (2%)	
Carcinoma, Metastatic, Pancreas				1 (2%)
Carcinoma, Metastatic, Uterus		1 (2%)		

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma				1 (2%)
Lymphoma Malignant	1 (2%)			

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

* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

Green tea extract

Time Report Requested: 09:47:59

Route: GAVAGE

CAS Number: GREENTEAEXTR

First Dose M/F: 07/18/07 / 07/19/07

Species/Strain: RATS/Wistar Han

Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	43	37	31	18
Total Primary Neoplasms	81	64	58	29
Total Animals with Benign Neoplasms	38	31	25	15
Total Benign Neoplasms	61	44	40	18
Total Animals with Malignant Neoplasms	16	19	17	8
Total Malignant Neoplasms	20	20	18	11
Total Animals with Metastatic Neoplasms	2	3	6	5
Total Metastatic Neoplasms	7	22	37	12
Total Animals with Malignant Neoplasms Uncertain Primary Site				1
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